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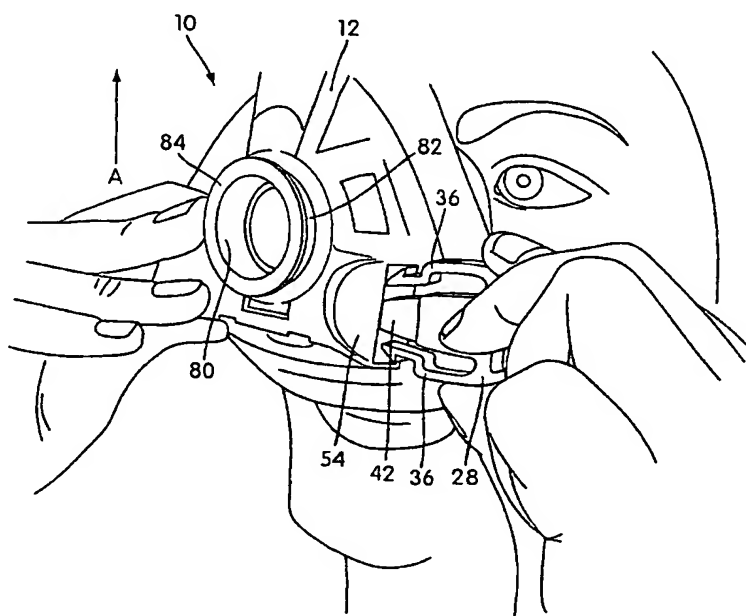
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(54) Title: **HEADGEAR CONNECTION ASSEMBLY FOR A RESPIRATORY MASK ASSEMBLY**



(57) Abstract: A respiratory mask assembly for delivering breathable gas to a patient has a frame (12) with a main body and lateral sides of the main body equipped with locking clip receiver means (54). A locking clip (28) is coupled to a headgear assembly at the rear portion and to the receiver means at the front portion. The rear portion has a cross bar forming an opening through which the headgear assembly can pass, whilst the front is provided with spring arms (36), flexible in the plane of the main body.

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**HEADGEAR CONNECTION ASSEMBLY FOR A
RESPIRATORY MASK ASSEMBLY**

CROSS-REFERENCE TO PRIORITY APPLICATIONS

The present application claims priority to U.S. Provisional Application Serial No. 60/424,698 filed November 8, 2002, U.S. Provisional Application Serial No. 60/467,571 filed May 5, 2003 and U.S. Non-Provisional Application Serial No. 10/235,846 filed September 6, 2002, which in turn claims priority to U.S. Provisional Application No. 60/317,486 filed September 7, 2001 and U.S. Provisional Application Serial No. 60/342,854 filed December 28, 2001. Each of the above applications is hereby incorporated herein by reference in its entirety.

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FIELD OF THE INVENTION

The present invention relates to a headgear connection assembly for use in removably attaching a headgear assembly to a frame of a respiratory mask assembly, the mask assembly being used for treatment, e.g., of Sleep Disordered Breathing (SDB) with Non-invasive Positive Pressure Ventilation (NPPV).

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BACKGROUND OF THE INVENTION

Respiratory mask assemblies used in the treatment of SDB may comprise a nasal mask designed to fit over a patient's nose, or a full face mask designed to fit over the nose and mouth of the patient. Air or other breathable gas is supplied by a blower and passed along a flexible conduit to the mask assembly.

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The mask assembly generally comprises a relatively rigid shell, e.g., a frame, which defines a rearwardly opening cavity covering the patient's nose and/or mouth, and a soft portion, e.g., a cushion, which spaces the frame away from the face of the patient for comfortable contact.

The mask assembly is usually held in place using a headgear assembly, the frame and headgear assembly being joined using some form of connector.

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One form of known connector is described in U.S. Patent No. 6,374,826 (Gunaratnam et al.). The contents of this patent are hereby incorporated by reference.

Some patients have poor dexterity, and hence find certain arrangements of connectors awkward or difficult to use. For example, some patients may have difficulty in correctly joining the frame and headgear assembly with the connector. As a result, the connector may

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disengage during use or may become stuck so it becomes difficult for the patient to disconnect the frame from the headgear assembly.

Furthermore, some connectors are positioned on the frame of the mask assembly which makes it difficult for the user to see the connectors, because they are very close to the eyes or
5 out of the range of vision of the patient. Hence, it is important to have a connector which is easy to use and which is easy to correctly assemble even if it is out of the range of vision of the patient.

SUMMARY OF THE INVENTION

One aspect of the present invention is to provide a respiratory mask assembly having a
10 headgear connection assembly positioned between the frame and headgear assembly in a convenient and intuitive location for quick attachment and/or detachment by the patient, while not being easily detached accidentally.

Another aspect of the present invention provides a respiratory mask assembly for delivering breathable gas to a patient. The respiratory mask assembly according to one
15 embodiment includes a frame and at least one locking clip. The frame has a main body and a side frame member provided on each lateral side of the main body. At least one of the side frame members includes an integrally formed locking clip receiver assembly. The at least one locking clip has a main body providing a front portion and a rear portion. The front portion is adapted to be removably coupled with the at least one locking clip receiver assembly and the
20 rear portion is adapted to be removably coupled to a headgear assembly. The rear portion of the locking clip includes a cross bar that forms an opening through which a strap of the headgear assembly can pass and be removably coupled with the cross bar, and the front portion of the locking clip includes at least one resiliently flexible spring arm that is flexible within the plane of the main body.

25 Another aspect of the invention is to provide a headgear connection assembly which can be easily molded in a mask frame which includes a swivel elbow connector.

Other aspects, features and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this
30 invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

Fig. 1 is a front perspective view illustrating a mask assembly having a headgear connection assembly constructed in accordance with an embodiment of the invention;

Fig. 2 is a front view of the mask assembly showing Fig. 1;

Fig. 3 is a top view of a locking clip of the headgear connection assembly shown in Fig. 1;

Fig. 4 is a perspective view of a locking clip of the headgear connection assembly shown in Fig. 1;

Fig. 5 is a perspective view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

Fig. 6 is a front view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

Fig. 7 is a cross-sectional view of a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

Fig. 8 is a cross-sectional view illustrating the engagement between a locking clip and a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

Fig. 9 is a cross-sectional view illustrating the engagement between a locking clip and a locking clip receiver assembly of the headgear connection assembly shown in Fig. 1;

Fig. 10 is a perspective view illustrating the mask assembly of Fig. 1 being secured to a patient's face by a headgear connection assembly of Fig. 1;

Fig. 11 is a top view illustrating the headgear connection assembly of Fig. 1 in a first incorrect position with respect to the frame of the mask assembly;

Fig. 12 is a top view illustrating the headgear connection assembly of Fig. 1 in a second incorrect position with respect to the frame of the mask assembly;

Fig. 13 is a front perspective view of a locking clip of the headgear connection assembly shown in Fig. 1;

Fig. 14 is a rear perspective view of the locking clip shown in Fig. 13;

Fig. 15 is a top view of the locking clip shown in Fig. 13;

Fig. 16 is a cross-section taken along line 16-16 of Fig. 15;

Fig. 17 is a front view of the locking clip shown in Fig. 13;

Fig. 18 is a rear view of the locking clip shown in Fig. 13;

Fig. 19 is a side view of the locking clip shown in Fig. 13;

Fig. 20 is a bottom view of the locking clip shown in Fig. 13;

Fig. 21 is a front perspective view of another embodiment of a locking clip;

Fig. 22 is a rear perspective view of the locking clip shown in Fig. 21;

5 Fig. 23 is a top view of the locking clip shown in Fig. 21;

Fig. 24 is a cross-section taken along line 24-24 of Fig. 23;

Fig. 25 is a front view of the locking clip shown in Fig. 21;

Fig. 26 is a rear view of the locking clip shown in Fig. 21;

Fig. 27 is a side view of the locking clip shown in Fig. 21;

10 Fig. 28 is a bottom view of the locking clip shown in Fig. 21;

Fig. 29 is a front perspective view illustrating an embodiment of a frame for a full-face mask assembly, the frame having a locking clip receiver assembly structured to interlock with the locking clip shown in Fig. 21;

15 Fig. 30 is a front perspective view, similar to Fig. 29 but at a different angle, of the frame shown in Fig. 29;

Fig. 31 is a rear perspective view of the frame shown in Fig. 29;

Fig. 32 is a front view of the frame shown in Fig. 29;

Fig. 33 is a side view of the frame shown in Fig. 29;

Fig. 34 is a top view of the frame shown in Fig. 29;

20 Fig. 35 is a top perspective view illustrating an embodiment of a forehead support adapted to be movably mounted to an upper portion of the frame shown in Fig. 29, the forehead support having a locking clip receiver assembly structured to interlock with the locking clip shown in Fig. 21;

Fig. 36 is a rear perspective view of the forehead support shown in Fig. 35;

25 Fig. 37 is a front perspective view of the forehead support shown in Fig. 35;

Fig. 38 is a front view of the forehead support shown in Fig. 35;

Fig. 39 is a side view of the forehead support shown in Fig. 35; and

Fig. 40 is a top view of the forehead support shown in Fig. 35.

30 DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

Figs. 1 and 2 shown a respiratory mask assembly 10 that includes a frame 12 and a cushion 14 that may be permanently or removably connected to the frame 12. For example, the cushion 14 may be removably attached to the frame 12 with a cushion clip, straps, a

friction or interference fit, and/or a tongue-in-groove arrangement, as is known in the art. However, the cushion 14 may be permanently attached to the frame 12 with glue and/or mechanical fastening means, for example.

A forehead support 16 is movably mounted to an upper portion of the frame 12. A
5 headgear assembly (not shown) can be removably attached to the frame 12 to maintain the frame 12 and cushion 14 in a desired adjusted position on the patient's face. For example, the headgear assembly may include a pair of upper and lower straps with the upper straps removably connected to clip structures 18 provided on the forehead support 16 and the lower straps removably connected the frame 12 by a headgear connection assembly 20, as will be
10 further discussed below.

In the illustrated embodiment, the mask assembly 10 is a nasal mask structure to deliver breathable gas to a patient's nose. However, the mask assembly 10 may be a nasal and mouth mask, or the mask assembly may be a full face mask.

A swivel elbow assembly 22 is removably attached to a front portion of the frame 12.
15 The elbow assembly 22 is structured to be connected to a conduit that is connected to a pressurized supply. The pressurized supply supplies pressurized breathable gas through the conduit and elbow assembly 22 and into the cushion 14 for breathing by the patient.

In the illustrated embodiment, lower straps of the headgear assembly are removably attached to the frame 12 by a headgear connection assembly 20. The headgear connection
20 assembly 20 includes a first connector portion 24 provided by the frame 12 and a second connector portion 26 adapted to be removably coupled with the first connector portion 24. The second connector portion 26 is removably connected to the lower straps of the headgear assembly.

As shown in Figs. 1-2, the second connector portion 26 includes a pair of locking clips
25 28. In a preferred embodiment, the locking clip 28 is a unitary plastic piece formed by injection molding. As shown in Figs. 3 and 4, each locking clip 28 includes a main body 30 having a rear portion 32 and a front portion 34. The rear portion 32 is removably connected to a lower strap of the headgear assembly and the front portion 34 is removably coupled with the first connector portion 24 provided on the frame 12.

30 Specifically, the front portion 34 includes at least one and preferably two resiliently flexible spring arms 36 that are attached to opposite sides of the main body 30 and extend away from the main body 30 in a generally parallel manner. However, the front portion 34 may include one spring arm 36. The spring arms 36 can flex up and down, e.g., in the

direction of arrows A or in a reverse direction of arrows A, respectively, as shown in Fig. 3. A locking tab 38 is attached to a free end of each spring arm 36. Further, each spring arm 36 is configured to provide a shoulder portion 40. In use, the shoulder portions 40 and locking tabs 38 are adapted to engage with corresponding portions of the first connector portion 24 for
5 coupling the first and second connector portions 24, 26 with one another. For example, the locking tabs 38 are structured to prevent accidental disengagement of the second connector portion 26 from the first connector portion 24 if a force is applied to the second connector portion 26 in the direction of arrow B (Fig. 3), as will be further discussed.

The front portion 32 also includes a central support tab 42 positioned between the pair
10 of spring arms 36. In the illustrated embodiment, the central support tab 42 has a length that is greater than the length of each of the spring arms 36. The central support tab 42 is slidably insertable into a complimentary shaped portion of the first connector portion 24, as will be further discussed.

As shown in Fig. 4, the central support tab 42 includes a groove 44. The central
15 support tab 42 has a height of h_2 , and the front portion of each spring arm 36 has a height of h_1 . In the illustrated embodiment, the height h_2 is larger than the height h_1 . In an alternative embodiment, h_2 may be smaller than h_1 .

The rear portion 32 of the second connector portion 26 includes a cross bar 46 that forms an opening 48 through which a lower strap of the headgear assembly may pass and be
20 removably connected. Specifically, an end portion of the lower strap of the headgear assembly may be wrapped around the cross bar 46. Fastening of the lower strap to the cross bar 46 may be assisted by use of a hook and loop material, such as Velcro®. Thus, the lower strap may be adjusted with respect to the locking clip 28 for proper fit. The locking clip 28 may be rotatably adjustable with respect to the headgear assembly, e.g., see U.S. Provisional Application No.
25 60/402,509, filed on August, 12, 2002, incorporated herein by reference in its entirety.

As shown in Figs. 1, 2, and 5, the frame 12 includes a main body 50 accommodating the cushion 14 and a side frame member 52 provided on each lateral side of the main body 50. Each side frame member 52 includes the first connector portion 24 which is integrally formed therewith. As shown in Figs. 5-7, the first connector portion 24 includes a locking clip
30 receiver assembly 54. The locking clip 28 is structured to interlock with the locking clip receiver assembly 54 to removably attach the locking clip 28, and hence the headgear assembly, to the frame 12.

Each locking clip receiver assembly 54 includes a slot 56 having a central portion 58 and two locking portions 60 positioned on opposite sides of the central portion 58. The central portion 58 of the slot 56 has an upper surface 62 that is continuous with an upper surface 64 of each of the locking portions 60. However, lower surfaces 66, 68 of the central portion 58 and two locking portions 60, respectively, have a stepped configuration. Specifically, as shown in Figs. 5 and 6, the central portion 58 has a height h_2 between the upper surface 62 and lower surface 66 thereof. The two locking portions 60 have a height h_1 between the upper surface 64 and lower surface 68 thereof. In the illustrated embodiment, the height h_2 is greater than the height h_1 . Moreover, the height h_2 of the central portion 58 is approximately equal to the height h_2 of the central support tab 42 and the height h_1 of the two locking portions 60 is approximately equal to the height h_1 of the front portion of each spring arm 36. This arrangement facilitates the connection between the locking clip 28 and the locking clip receiver assembly 54, as will be further discussed.

As shown in Fig. 7, each of the locking portions 60 includes a locking flange 70 positioned on an outer wall thereof for engagement with the locking tab 38 of a locking clip 28.

The central portion 58 includes a wall 72 that extends upwardly from the lower surface 66 towards the upper surface 62. In the illustrated embodiment, the wall 72 extends approximately half the way to the upper surface 62.

In the illustrated embodiment, the first connector portions 24 are integrally molded with the frame 12. As shown in Figs. 5 and 10, the frame 12 also includes an orifice 80 and collar 82 adapted to receive a swivel elbow 22 (Figs. 1 and 2). The collar 82 has a rim 84 which extends horizontally and radially from the orifice 80. In order to form the collar 82, it is advantageous if the mold can be withdrawn horizontally. However, it is desirable that the headgear be presented at an angle with respect to the frame 12. The first connector portions 24 are aligned downwardly at an angle θ of approximately 5% with respect to the horizontal. When the frame 12 is molded, the mold components should be withdrawn in a horizontal direction to form the collar 82. As shown in Fig. 7, the junction between the lower surfaces 66, 68 of the central portion 58 and locking portions 60, respectively, is arranged to make an angle α which is sufficiently wide to enable the sides of the mold to be withdrawn in a horizontal direction. Further, the angled junction facilitates the connection between the locking clip 28 and the locking clip receiver assembly 54.

As shown in Fig. 9, the front portion 34 and rear portion 32 of the locking clip 28 are disposed at an angle β with respect to one another. In the illustrated embodiment, the rear

portion 34 is angled downwardly with respect to the horizontal, whereas the front portion 32 is generally horizontally aligned. By use of this angle, the locking clip 28 does not protrude as far from the mask as it would otherwise. Furthermore, the headgear straps are connected to the locking clip 28 at an angle which more naturally follows the contour of the face. In an
5 alternative form of the invention, the front and rear portions 34, 32 may be curved to achieve an angular difference between the front and rear. An advantage of either approach is that the slot 56 of the first connector portion 24 into which the front portion 34 of the second connector 26 is slidably received may be generally horizontal. This is advantageous during the manufacture process because it means the sides of the mold may be withdrawn horizontally to
10 assist formation of the collar 82.

As shown in Figs. 8-9, the locking portions 60 of the slot 56 are adapted to receive a respective one of the pair of spring arms 36, the locking tab 38 of each spring arm 36 interlocking with the locking flange 70 provided in respective locking portions 60 to
15 removably attach the locking clip 28, and hence the headgear assembly, to the frame 12. The shoulder portion 40 of each locking clip 28 engages an engagement face 74 provided on the frame 12 when the locking clip 28 is inserted into the locking clip receiver assembly 54 to provide additional support for the locking clip 28. The locking tab 38 may interlock with an undercut provided in the locking portions 60 to removably attach the locking clip 28 to the
20 frame 12. Further, each locking tab 38 may extend through a slot provided in the outer wall of the locking portion 60. The slot need not extend through the outer wall of the locking portion 60.

The central support tab 42 is inserted into the central portion 58 of the slot 56 when the locking clip 28 and locking clip receiver assembly 54 are engaged so as to prevent relative movement between the locking clip 28 and the locking clip receiver assembly 54.

25 Specifically, when the locking clip 28 is inserted into the locking clip receiver assembly 54, the spring arms 36 are forced toward one another (in the direction of arrows A as shown in Fig. 3) as the locking tabs 38 are inserted into respective locking portions 60 of the slot 56 and ride up and over the locking flanges 70. Once the locking tabs 38 have cleared respective locking flanges 70, the spring arms 36 can spring outwardly (in the reverse direction of arrows
30 A as shown in Fig. 3) to provide a locking engagement between the locking tabs 38 and the locking flanges 70. Sufficient clearance is provided in the locking portions 60 of the slot 56 to allow the necessary movement of the locking tabs 38 to clear the locking flanges 70.

The central support tab 42 is configured to have a close fit with the central portion 58 of the slot 56 so that when the central support tab 42 is inserted into the central portion 58, little rotational, rocking or side-to-side movement is permitted between the locking clip 28 and the locking clip receiver assembly 54. The central support tab 42 is longer than the spring arms 36 to assist with alignment into the slot 56. Further, the groove 44 of the central support tab 42 engages the wall 72 provided in the central portion 58 of the slot 56 to facilitate entry of the central support tab 42 into the central portion 58 of the slot 56. Alternatively, the central support tab 42 may have a protrusion that engages a groove provided in the central portion 58 of the slot 56. Also, the central support tab 42 has a shape that is complementary to the angle α that defines the shape of the central portion 58 of the slot 56.

Because the height h_2 of the central portion 58 is approximately equal to the height h_2 of the central support tab 42 and the height h_1 of the two locking portions 60 is approximately equal to the height h_1 of the front portion of each spring arm 36, the locking portions 60 of the slot 56 are of sufficient height to accommodate the front portion of each spring arm 36, but insufficient to accommodate the central support tab 42. That is, the central support tab 42 is too thick to fit into the locking portions 60 of the slot 56. Because of this arrangement, it will be clear to the patient whether or not the locking clip 28 has been correctly engaged with the locking clip receiver assembly 54. Thus, the patient cannot inadvertently partly assemble the locking clip 28 to the locking clip receiver assembly 54 in such a way that it will accidentally release. For example, Fig. 11 illustrates a first incorrect position of the locking clip 28 with respect to the locking clip receiver assembly 54 and Fig. 12 illustrates a second incorrect position of the locking clip 28 with respect to the locking clip receiver assembly 54. In both instances, the patient is unable to insert the thicker central support tab 42 into the thinner locking portion 60 of the slot 56.

To release the locking clip 28 from the locking clip receiver assembly 54, the patient simply forces the spring arms 36 towards one another to clear the locking tabs 38 from respective locking flanges 70. Then, the patient pulls the locking clip 28 outwardly away from the frame 12 to disengage the locking clip 28 from the locking clip receiver assembly 54.

As shown in Fig. 8, the locking tabs 38 and central support tab 42 have rounded or contoured edges to facilitate entry into the slot 56. Also, the outward surfaces of the locking clip 28 and the frame 12 preferably form a generally coextensive continuous surface, which is not interrupted when connected. Preferably, the locking clip 28 is as wide as the side frame members 52, which facilitates tactile location of the locking clip 28 by the patient.

The spring arms 36 are designed to flex within the plane of the locking clip main body 30, which further improves the ease by which the locking clips 28 are attached and detached. This positioning improves the ergonomics of flexing the spring arms up and down. As shown in Fig. 10, the patient's thumb and opposing finger can be used to readily locate and operate the locking clips 28. The outward surface of the spring arms 36 may include a series of protrusions 76 to facilitate gripping of the locking clip 28 by the patient (see Fig. 8). Further, the locking clips 28 are connected to the straps of the headgear assembly so that length adjustment may be provided.

An advantage of the headgear connection assembly 20 is that one locking clip 28 can be used with the locking clip receiver assembly 54 provided on each side frame member 52, thereby reducing manufacturing costs and the need for inventory.

Figs. 13-20 show further structural details in various dimensions in one embodiment of the locking clip 28 of the headgear connection assembly 20. For example, the locking clip 28 has a length in the range of 20-40 mm, preferably 29 mm, a width in the range of 20-40 mm, preferably 27.8 mm, and a height in the range of 4-8 mm, preferably 6.7 mm. In an embodiment of the locking clip 28, the dimensions illustrated in Figs. 13-20 may vary $\pm 10\%$.

In the illustrated embodiment, the rear portion 32 of the locking clip 28 includes a cross-bar 46 that forms an opening 48 through which a strap of the headgear assembly can be removably coupled with the cross-bar 46. In other forms of the invention, the strap of the headgear assembly is connected using other mechanisms. For example, the strap may include a hook which engages with a corresponding hole in the locking clip. In another form, the strap is sewn in position and is not removable. In another form, the strap is removable, and held in position by a friction fit.

In the illustrated embodiment, a locking clip in accordance with the invention is used only on a mask frame adjacent a swivel elbow, in the region of the mouth; and straps for connection to a forehead support of the mask assembly are held in position only by hook & loop material. Thus two locking clips are used on one mask. In another embodiment of the invention, four locking clips are used, two as illustrated, and a further two being used as part of the forehead support.

Figs. 21-28 illustrate another embodiment of a locking clip, indicated as 228. As shown in Figs. 29-40, the locking clip 228 is structured for use with a full-face mask assembly having a frame 212 (see Figs. 29-34) and a forehead support 216 (see Figs. 35-40). Specifically, as shown in Figs. 29-34, the frame 212 has a pair of locking clip receiver

assemblies 254 structured to interlock with a pair of locking clips 228. As shown in Figs. 35-40, the forehead support 216 has a pair of locking clip receiver assemblies 254 structured to interlock with a pair of locking clips 228. However, the locking clip 228 and locking clip receiver assemblies 254 illustrated may be structured for use with a nasal mask or a nasal and mouth mask, for example.

As shown in Figs. 21-28, the locking clip 228 is substantially similar to the locking clip 28 described above. In contrast, the length of the groove 244 provided in clip 228 is greater than the length of the groove 44 provided in clip 28, as will be further discussed. The remaining elements of the locking clip 228 are similar to the elements of the locking clip 28 and are indicated with similar reference numerals.

Similar to the previous embodiment, the locking clip 228 includes a main body 230 having a rear portion 232 and a front portion 234. The rear portion 232 is removably connected to a strap of the headgear assembly and the front portion 234 is removably coupled with a respective locking clip receiver assembly 254 provided on the frame 212 or forehead support 216. The front portion 234 includes two resiliently flexible spring arms 236 that are attached to opposite sides of the main body 230. The flexible spring arms 236 are flexible within the plane of the main body 230.

Further, each spring arm 236 includes a locking tab 238 and a shoulder portion 240 adapted to engage with a respective locking clip receiver assembly 254 provided on the frame 212 or forehead support 216. As best shown in Figs. 22 and 28, the front portion 234 also includes a central support tab 242 that includes a groove 244.

The groove 244 provided in clip 228 is deeper or more elongated than the groove 44 provided in clip 28 (as best shown in Figs. 14 and 22). In the illustrated embodiment, the groove 244 has a length that is at least half a length of the central support tab 242. The elongated groove in clip 228 facilitates with alignment of the clip 228 with the frame 212 or forehead support 216. Moreover, the elongated groove 244 helps to prevent relative movement between the locking clip 228 and the respective locking clip receiver assembly 254 on the frame 212 or forehead support 216, as will be further discussed below.

Figs. 29-34 show an embodiment of a frame 212 for a full-face mask assembly. The frame 212 may be permanently or removably connected to a cushion (not shown) in any suitable manner. Further, a swivel elbow assembly (not shown) may be removable attached to a front portion of the frame 212.

Each lateral side of the frame 212 includes a locking clip receiver assembly 254 structured to interlock with a locking clip 228. Similar to locking clip receiver assembly 54, the locking clip receiver assembly 254 includes a slot 256 having a central portion 258 and two locking portions 260. The locking portions 260 include a locking flange 270 (see Fig. 32) positioned on an outer wall thereof for engagement with the locking tab 238 of a locking clip 228. In the illustrated embodiment, an upper wall 261 of the slot 256 includes a pair of openings 263 that are aligned with the locking flange 270. This enables the patient to visually confirm that the locking tab 238 of a locking clip 228 is interlocked with the locking flange 270 in use.

Also, the central portion 258 includes a wall 272. As best shown in Figs. 29, 30, and 32, the wall 272 provided in the locking clip receiver assembly 254 extends outwardly away from the slot 256. In the embodiment of locking clip receiver assembly 54, the wall 72 was positioned entirely within the slot 56 (see Figs. 5, 7, 11, and 12). The elongated wall 272 of locking clip receiver assembly 254 facilitates alignment of a clip 228 with a respective locking clip receiver assembly 254. Specifically, the groove 244 of a clip 228 may be engaged with the elongated wall 272 so as to guide the clip 228 into the slot 256.

Moreover, when a clip 228 is engaged with a respective locking clip receiver assembly 254, the engagement between the elongated groove 244 of the clip 228 and the wall 272 of the locking clip receiver assembly 254 prevents rocking or side-to-side movement between the clip 228 and locking clip receiver assembly 254. Further, any force applied to one of the spring arms 236 of the clip 228, when the clip 228 is engaged with the locking clip receiver assembly 254, will not be transferred to the other spring arm 236 of the clip 228. Thus, the clip 228 is prevented from being inadvertently disengaged from the respective locking clip receiver assembly 254 in use. To release the locking clip 228 from the locking clip receiver assembly 254, both spring arms 236 must be forced towards one another to clear the locking tabs 238 from respective locking flanges 270.

Figs. 35-40 show an embodiment of a forehead support 216 adapted to be movably mounted to an upper portion of the frame 212. The forehead support 216 may be permanently or removably connected to a forehead pads (not shown) in any suitable manner.

Each lateral side of the forehead support 216 includes a locking clip receiver assembly 254 structured to interlock with a locking clip 228. The locking clip receiver assembly 254 on the forehead support 216 is substantially similar to the locking clip receiver assembly on the frame 216 and indicated with similar reference numerals. As a result, one locking clip 228 can

be used with the locking clip receiver assemblies 254 provided on the frame 212 and the forehead support 216, thereby reducing manufacturing costs and the need for inventory. Thus, four locking clips 228 are used, two locking clips 228 for the frame 212 and two locking clips 228 for the forehead support 216. In use, upper straps of a headgear assembly would be
5 removably connected to the locking clips 228 for the forehead support 216 and lower straps of the headgear assembly would be removably connected to locking clips 228 for the frame 212.

It can thus be appreciated that the aspects of the present invention have been fully and effectively accomplished. The foregoing specific embodiments have been provided to illustrate the structural and functional principles of the present invention, and are not intended
10 to be limiting. To the contrary, the present invention is intended to encompass all modifications, alterations and substitutions within the spirit and scope of the present invention.

WHAT IS CLAIMED IS:

- 1 1. A respiratory mask assembly for delivering breathable gas to a patient,
2 comprising:
3 a frame having a main body and a side frame member provided on each lateral
4 side of the main body, at least one of the side frame members including an integrally formed
5 locking clip receiver assembly; and
6 at least one locking clip having a main body providing a front portion and a
7 rear portion, the front portion adapted to be removably coupled with the at least one locking
8 clip receiver assembly and the rear portion adapted to be removably coupled to a headgear
9 assembly,
10 wherein the rear portion of the locking clip includes a cross bar that forms an
11 opening through which a strap of the headgear assembly can pass and be removably coupled
12 with the cross bar, and the front portion of the locking clip includes at least one resiliently
13 flexible spring arm that is flexible within the plane of the main body.
- 1 2. A respiratory mask assembly according to claim 1, wherein the locking clip
2 receiver assembly includes a slot and the spring arm includes a locking tab at a free end
3 thereof, the locking tab configured to be inserted into the slot and interlocked with the
4 locking flange provided within the slot to removably couple the locking clip to the locking
5 clip receiver assembly.
- 1 3. A respiratory mask assembly according to claim 1, wherein the locking clip
2 receiver assembly includes a slot and the locking clip includes a central support tab that is
3 inserted into the slot when the locking clip and locking clip receiver assembly are removably
4 coupled so as to prevent relative movement between the locking clip and the locking clip
5 receiver assembly.
- 1 4. A respiratory mask assembly according to claim 3, wherein the locking clip
2 includes a pair of spring arms, the central support tab being positioned between the pair of
3 spring arms and having a length that is greater than a length of each of the spring arms.

1 5. A respiratory mask assembly according to claim 4, wherein the slot includes a
2 locking portion and a central portion, the at least one spring arm being insertable into the
3 locking portion of the slot and the central support tab being insertable into the central portion
4 of the slot.

1 6. A respiratory mask assembly according to claim 5, wherein the locking
2 portion of the slot has a height approximately equal to a height of a front portion of the at
3 least one spring arm, and the central portion of the slot has a height approximately equal to a
4 height of the central support tab.

1 7. A respiratory mask assembly according to claim 6, wherein the height of the
2 locking portion is less than the height of the central portion to prevent the central support tab
3 from being inserted into the locking portion of the slot.

1 8. A respiratory mask assembly according to any one of claims 4-7, wherein the
2 slot includes a protrusion and the central support tab includes a groove, the protrusion being
3 inserted into the groove when the locking clip and locking clip receiver assembly are
4 removably coupled to one another.

1 9. A respiratory mask assembly according to claim 8, wherein the protrusion
2 extends outwardly away from the slot.

1 10. A respiratory mask assembly according to claim 8, wherein the groove has a
2 length that is at least half a length of the central support tab.

1 11. A respiratory mask assembly according to claim 8, wherein a force applied to
2 one of the pair of spring arms is not be transferred to the other of the pair of spring arms due
3 to the engagement between the groove of the central support tab and the protrusion of the
4 slot.

1 12. A respiratory mask assembly according to any one of claims 1-11, wherein the
2 locking clip is configured to allow the patient to grasp the same between the thumb and
3 forefinger of the patient.

1 13. A respiratory mask assembly according to any one of claims 1-12, wherein
2 both side frame members include a locking clip receiver assembly, and the mask assembly
3 includes a pair of locking clips adapted to be removably coupled with a respective one of the
4 locking clip receiver assemblies.

1 14. A respiratory mask assembly according to any one of claims 1-13, wherein the
2 mask assembly is a nasal mask.

1 15. A locking clip for removably coupling a frame and a headgear assembly of a
2 respiratory mask assembly for delivering breathable gas to a patient, the locking clip
3 comprising:
4 a main body providing a front portion and a rear portion, the front portion
5 adapted to be removably coupled with the frame and the rear portion adapted to be removably
6 coupled to the headgear assembly,
7 wherein the rear portion includes a cross bar that forms an opening through
8 which a strap of the headgear assembly can pass and be removably coupled with the cross
9 bar, and the front portion includes at least one resiliently flexible spring arm that is flexible
10 within the plane of the main body.

1 16. The locking clip according to claim 15, wherein the spring arm includes a
2 locking tab at a free end thereof, the locking tab configured to be inserted into a slot of the
3 frame and interlocked with a locking flange provided within the slot to removably couple the
4 locking clip to the frame.

1 17. The locking clip according to claim 15, wherein the locking clip includes a
2 central support tab that is inserted into a slot of the frame when the locking clip and frame are
3 removably coupled so as to prevent relative movement between the locking clip and the
4 frame.

1 18. The locking clip according to claim 17, wherein the locking clip includes a
2 pair of spring arms, the central support tab being positioned between the pair of spring arms
3 and having a length that is greater than a length of each of the spring arms.

1 19. The locking clip according to claim 18, wherein the central support tab
2 includes a groove that receives a protrusion provided in the slot when the locking clip and
3 frame are removably coupled to one another.

1 20. The locking clip according to claim 19, wherein the groove has a length that is
2 at least half a length of the central support tab.

1 21. The locking clip according to any one of claims 19-20, wherein a force applied
2 to one of the pair of spring arms is not be transferred to the other of the pair of spring arms
3 due to the engagement between the groove of the central support tab and the protrusion of the
4 slot.

1 22. The locking clip according to any one of claims 17-21, wherein the central
2 support tab has a height that is greater than a height of a front portion of the at least one
3 spring arm.

1 23. The locking clip according to any one of claims 15-22, wherein the locking
2 clip is configured to allow the patient to grasp the same between the thumb and forefinger of
3 the patient.

1 24. A respiratory mask assembly for delivering breathable gas to a patient,
2 comprising:
3 a frame having a main body and a side frame member provided on each lateral
4 side of the main body, at least one of the side frame members including an integrally formed
5 locking clip receiver assembly; and
6 at least one locking clip having a main body providing a front portion and a
7 rear portion, the front portion adapted to be removably coupled with the at least one locking

8 clip receiver assembly and the rear portion adapted to be removably coupled to a headgear
9 assembly,
10 wherein the front portion and rear portion of the at least one locking clip are
11 disposed at an angle with respect to one another.

1 25. A respiratory mask assembly according to claim 24, wherein the front portion
2 is generally aligned with the at least one locking clip receiver assembly when the front
3 portion is removably coupled with the at least one locking clip receiver assembly and the rear
4 portion is angled with respect to the front portion such that the rear portion extends towards
5 the patient's face when the mask assembly is secured to the patient's face.

1 26. A respiratory mask assembly according to claim 24, wherein the rear portion
2 of the locking clip includes a cross bar that forms an opening through which a strap of the
3 headgear assembly can pass and be removably coupled with the cross bar, and the front
4 portion of the locking clip includes at least one resiliently flexible spring arm that is flexible
5 within the plane of the main body.

1 27. A respiratory mask assembly for delivering breathable gas to a patient,
2 comprising:
3 a frame having a main body and a side frame member provided on each lateral
4 side of the main body,
5 the main body providing an orifice therethrough for the introduction of
6 breathable gas into a nasal breathing cavity and a collar that substantially surrounds the
7 orifice,
8 at least one of the side frame members including an integrally formed locking
9 clip receiver assembly,
10 wherein the frame is formed by molding such that mold components of a mold
11 can be withdrawn along a single plane to separate the mold from the collar and the locking
12 clip receiver assembly.

1 28. A respiratory mask assembly according to claim 27, further comprising an
2 elbow assembly coupled to the collar.

1 29. A respiratory mask assembly according to any one of claims 27-28, further
2 comprising at least one locking clip having a main body providing a front portion and a rear
3 portion, the front portion adapted to be removably coupled with the at least one locking clip
4 receiver assembly and the rear portion adapted to be removably coupled to a headgear
5 assembly.

1 30. A respiratory mask assembly according to claim 29, wherein the rear portion
2 of the locking clip includes a cross bar that forms an opening through which a strap of the
3 headgear assembly can pass and be removably coupled with the cross bar, and the front
4 portion of the locking clip includes at least one resiliently flexible spring arm that is flexible
5 within the plane of the main body.

1 31. A method for molding a frame for a respiratory mask assembly, the method
2 comprising:
3 molding a frame in a mold to include a main body and a side frame member
4 provided on each lateral side of the main body, the main body defining an orifice
5 therethrough and a collar that substantially surrounds the orifice;
6 forming at least one locking clip receiver assembly on at least one of the side
7 frame members; and
8 withdrawing opposed mold components of the mold along a single plane to
9 separate the mold from the collar and the locking clip receiver assembly.

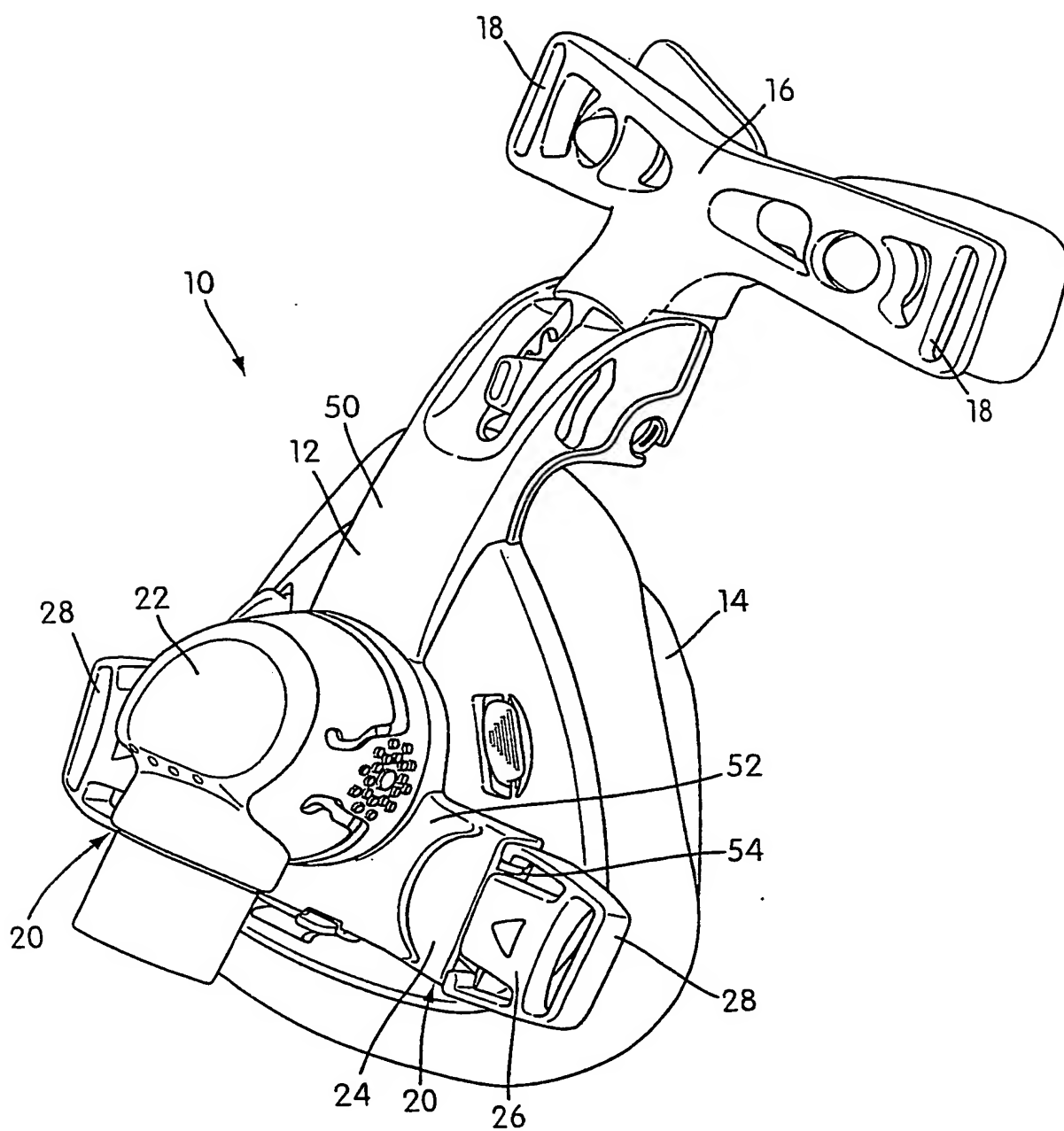


FIG. 1

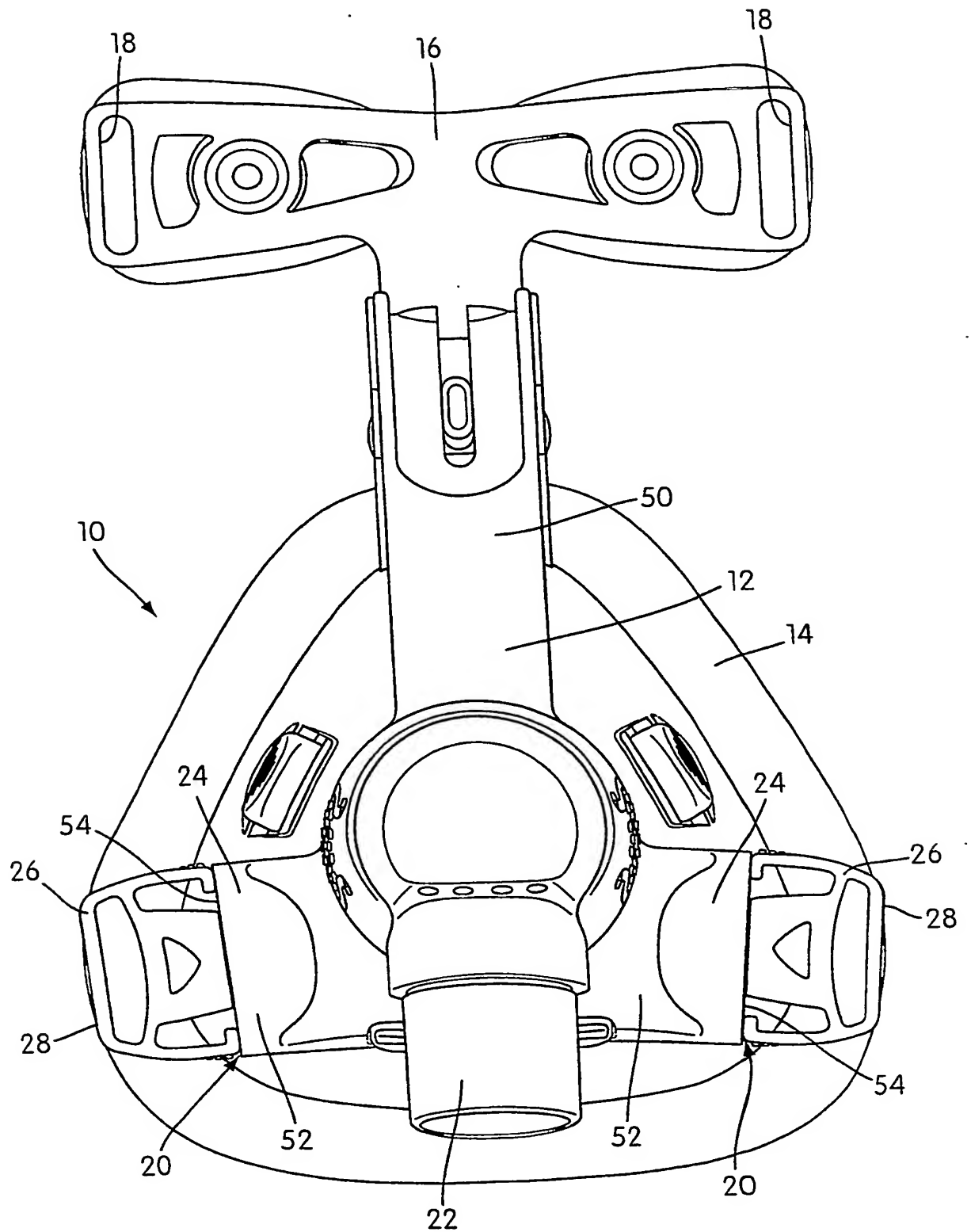


FIG. 2

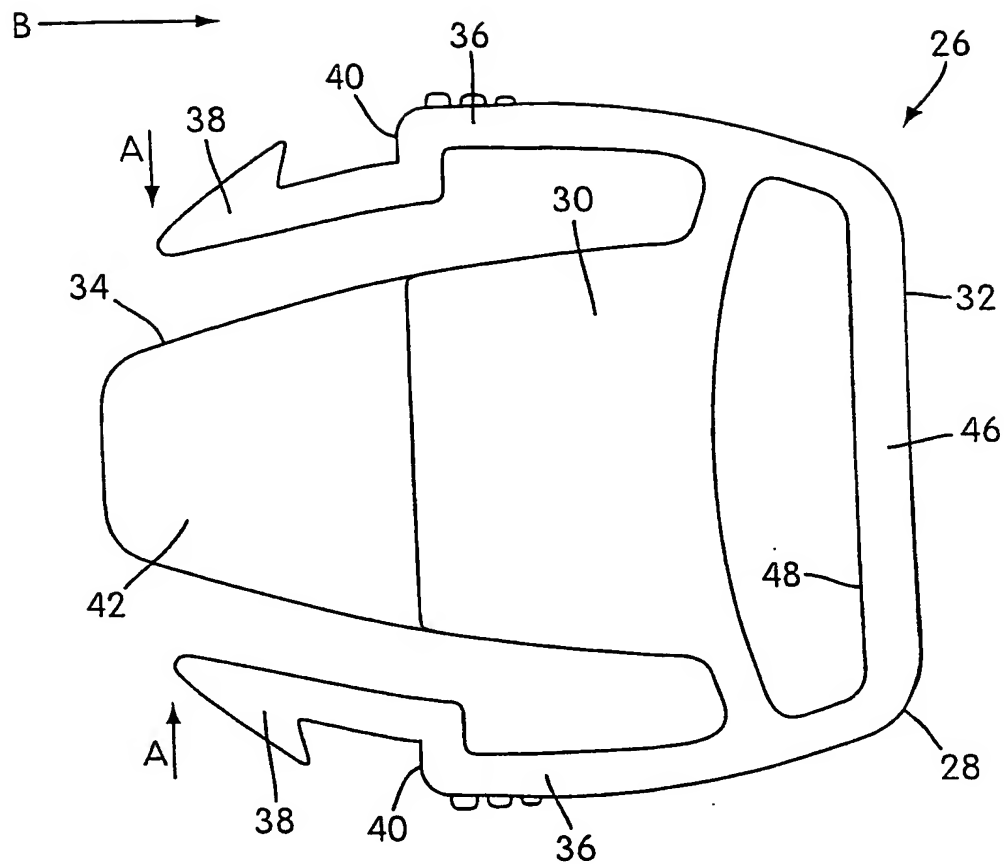


FIG. 3

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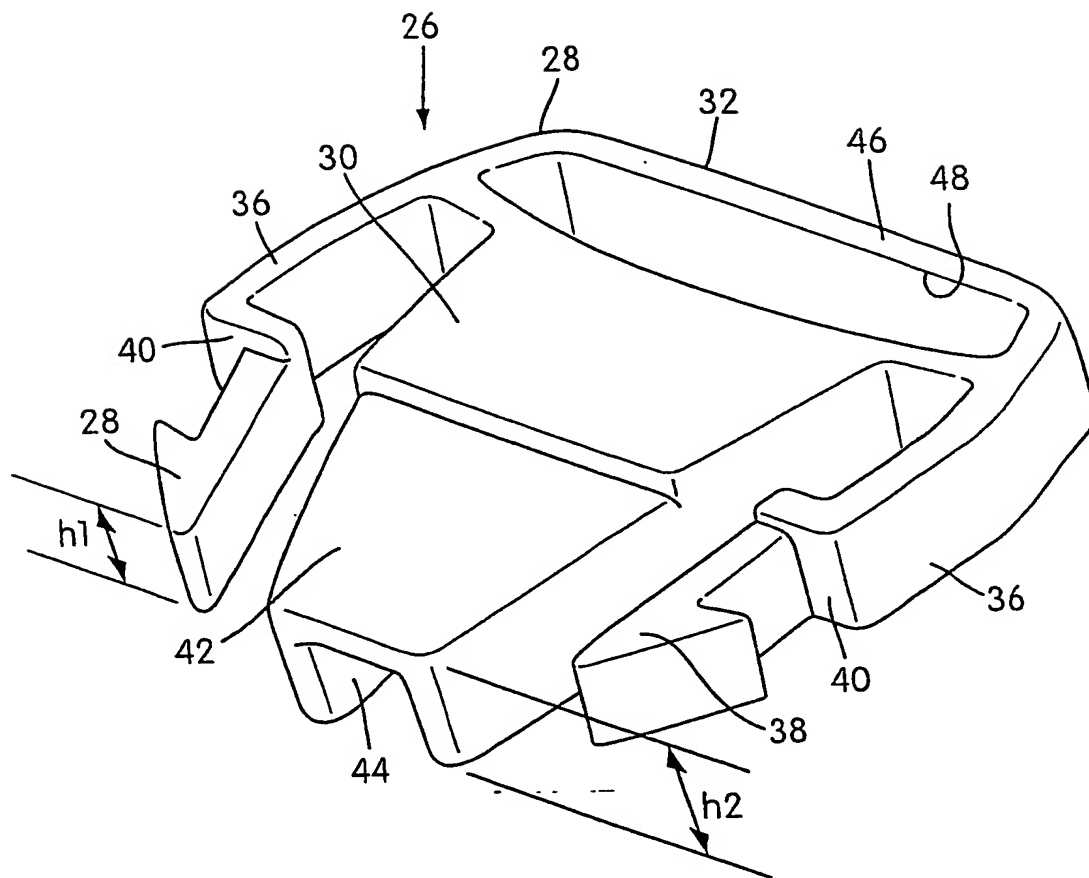


FIG. 4

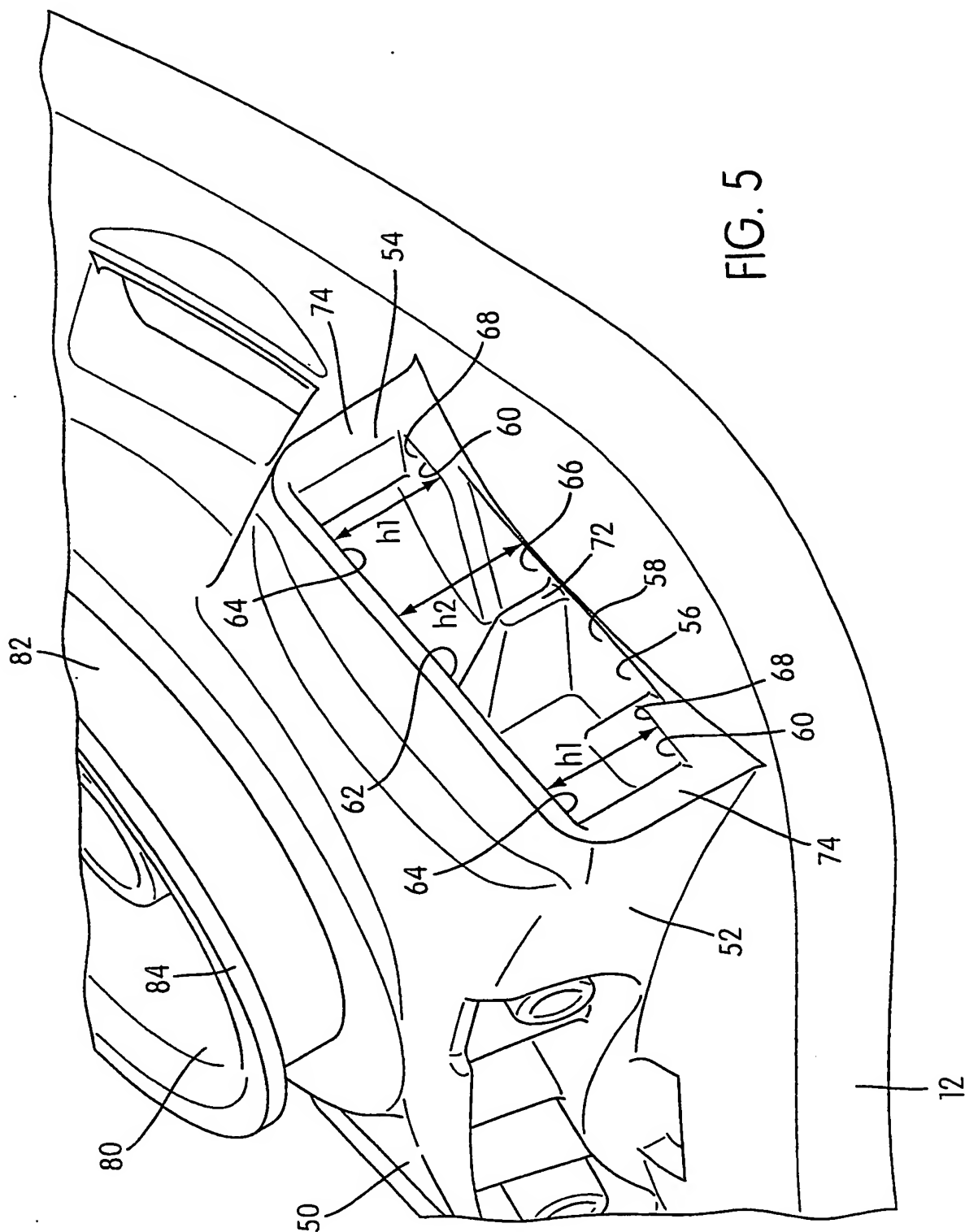


FIG. 5

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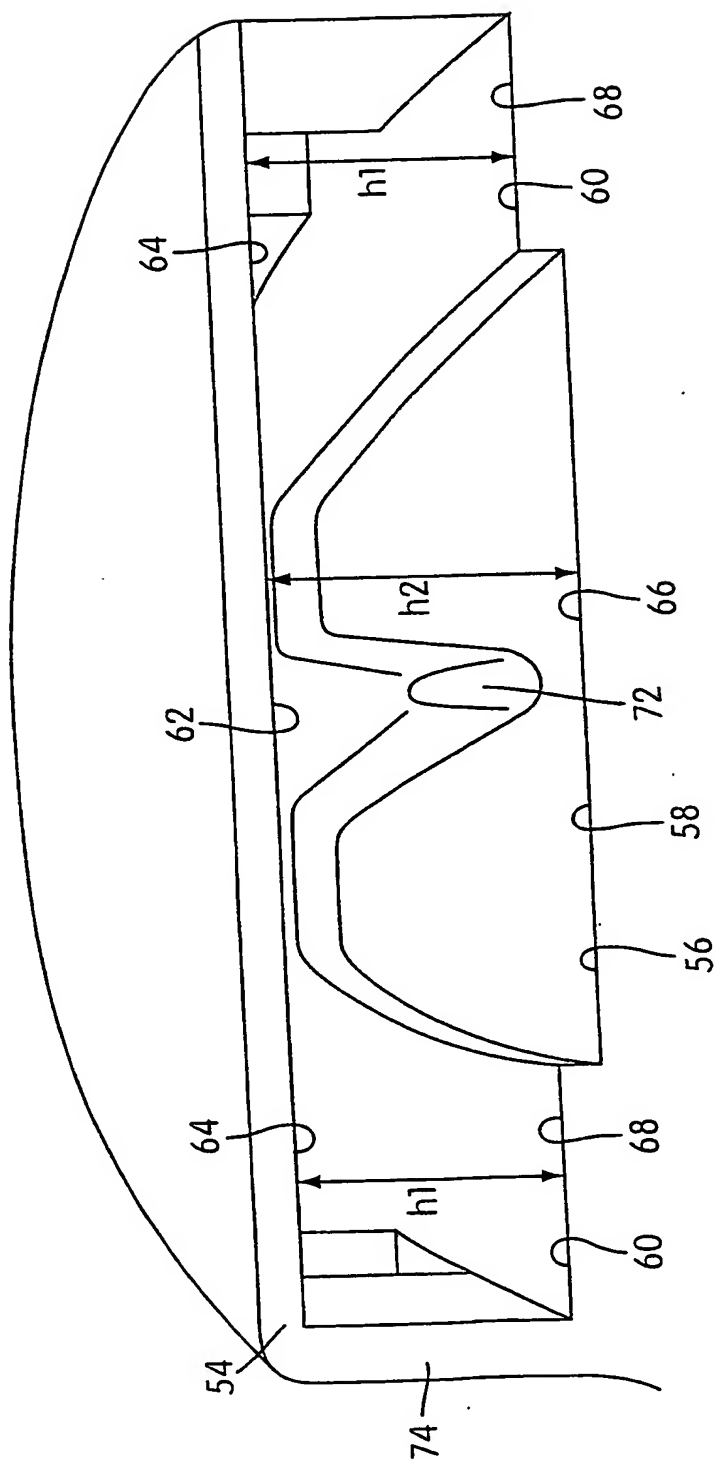


FIG. 6

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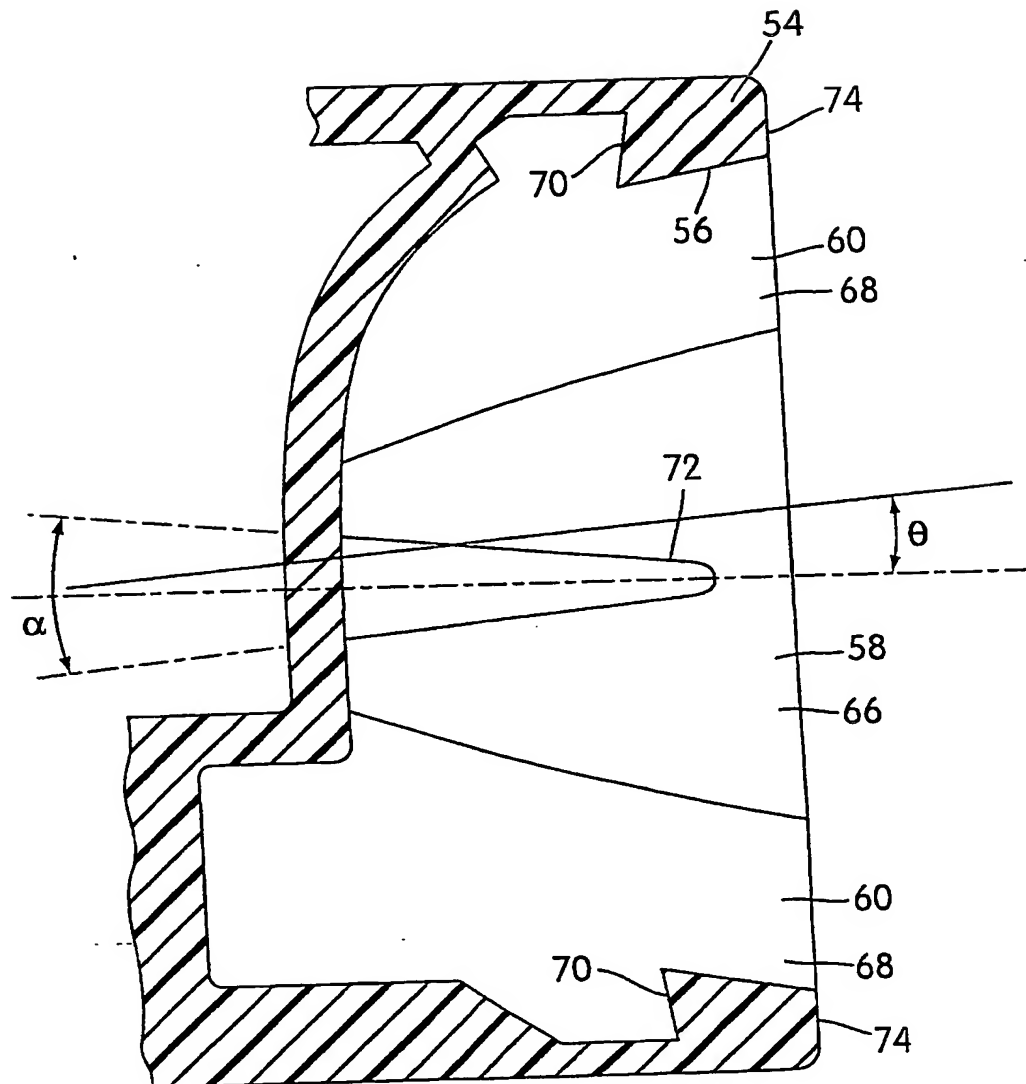


FIG. 7

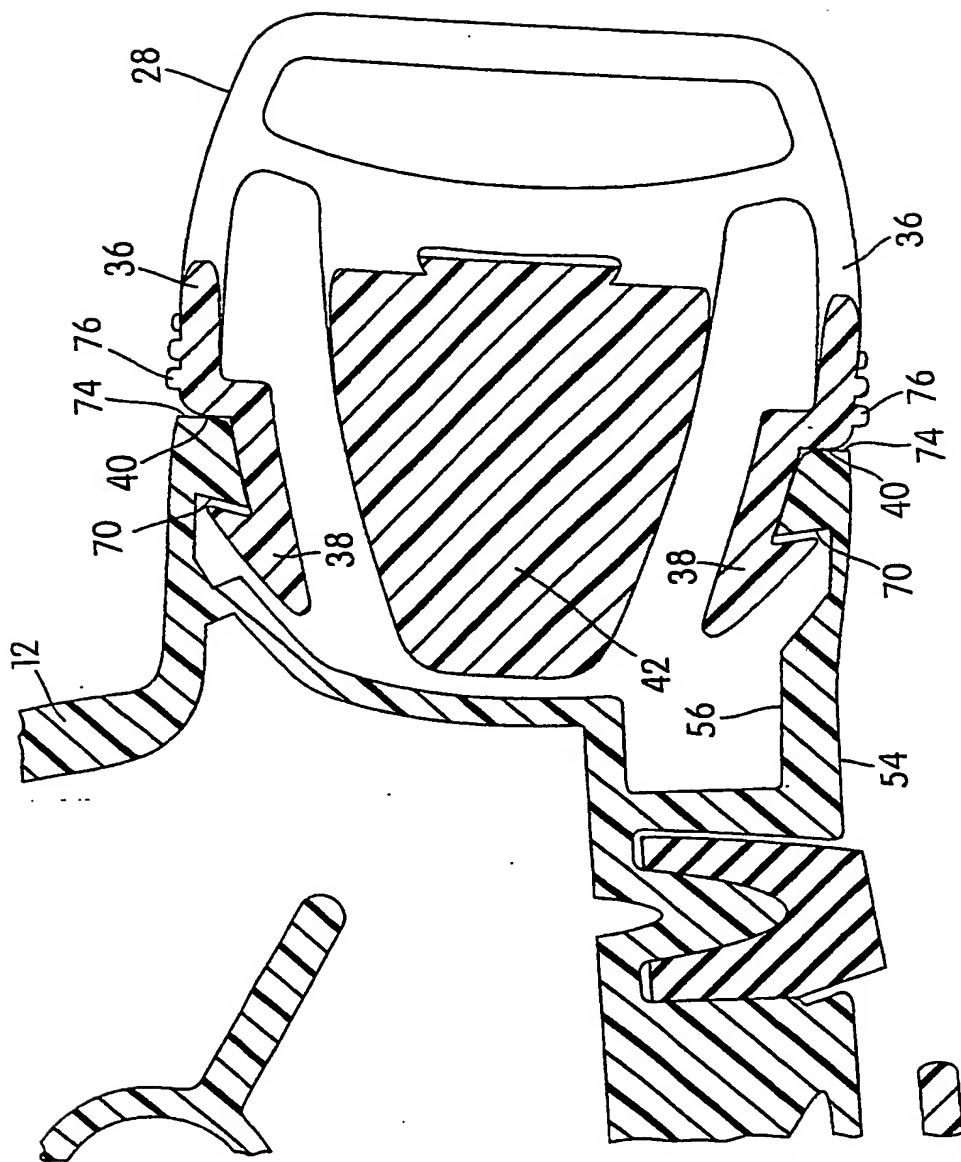


FIG. 8

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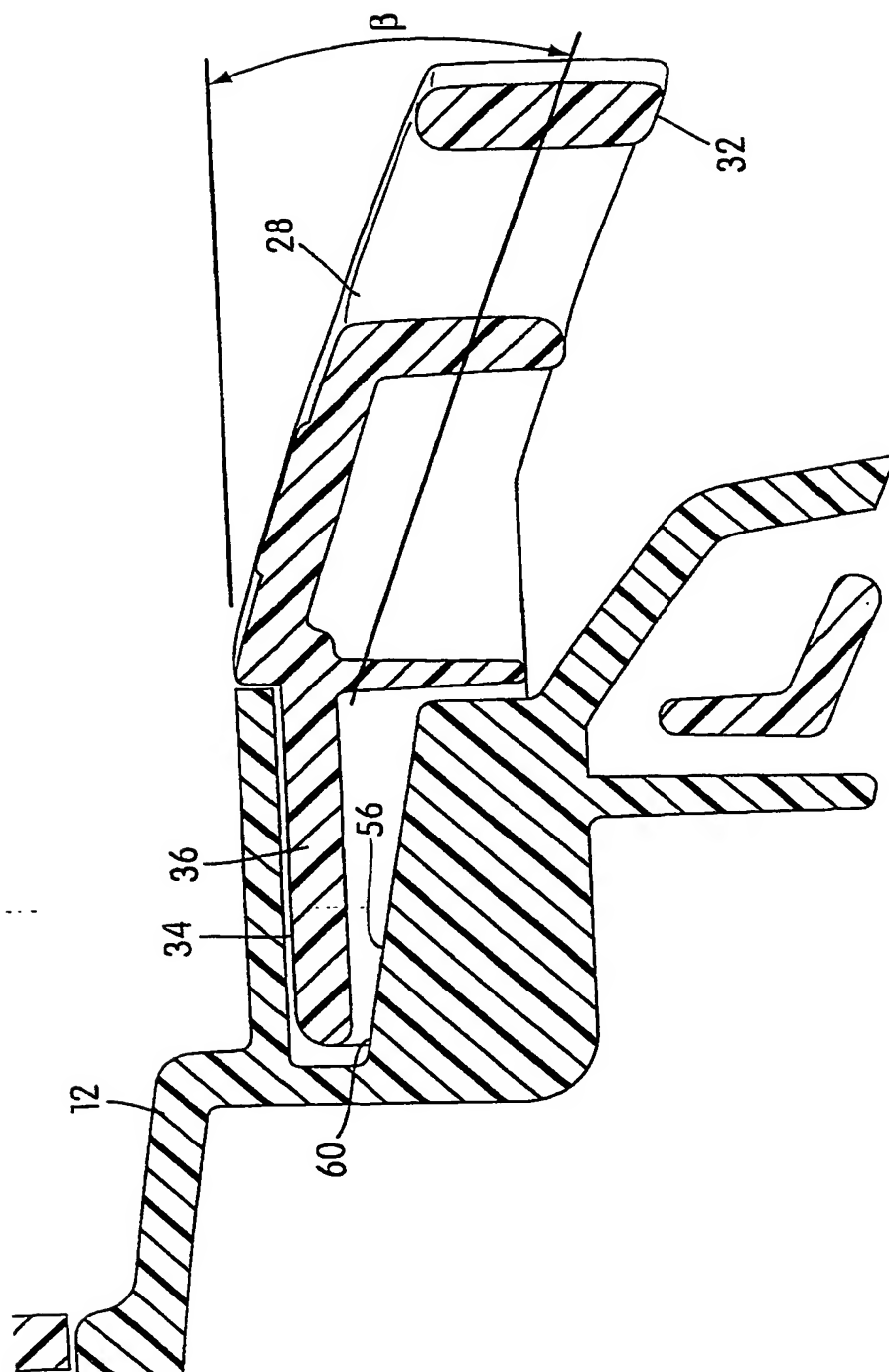


FIG. 9

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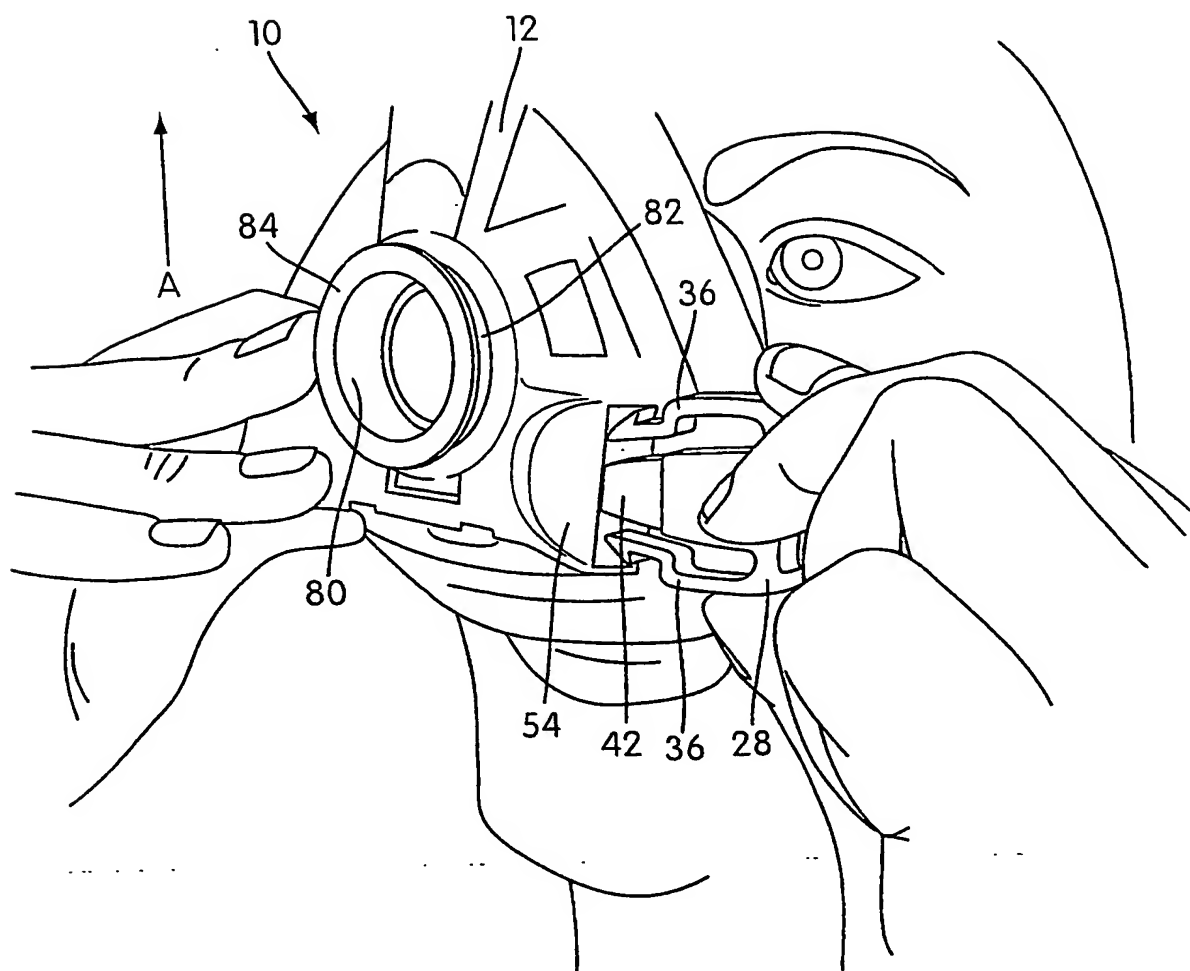
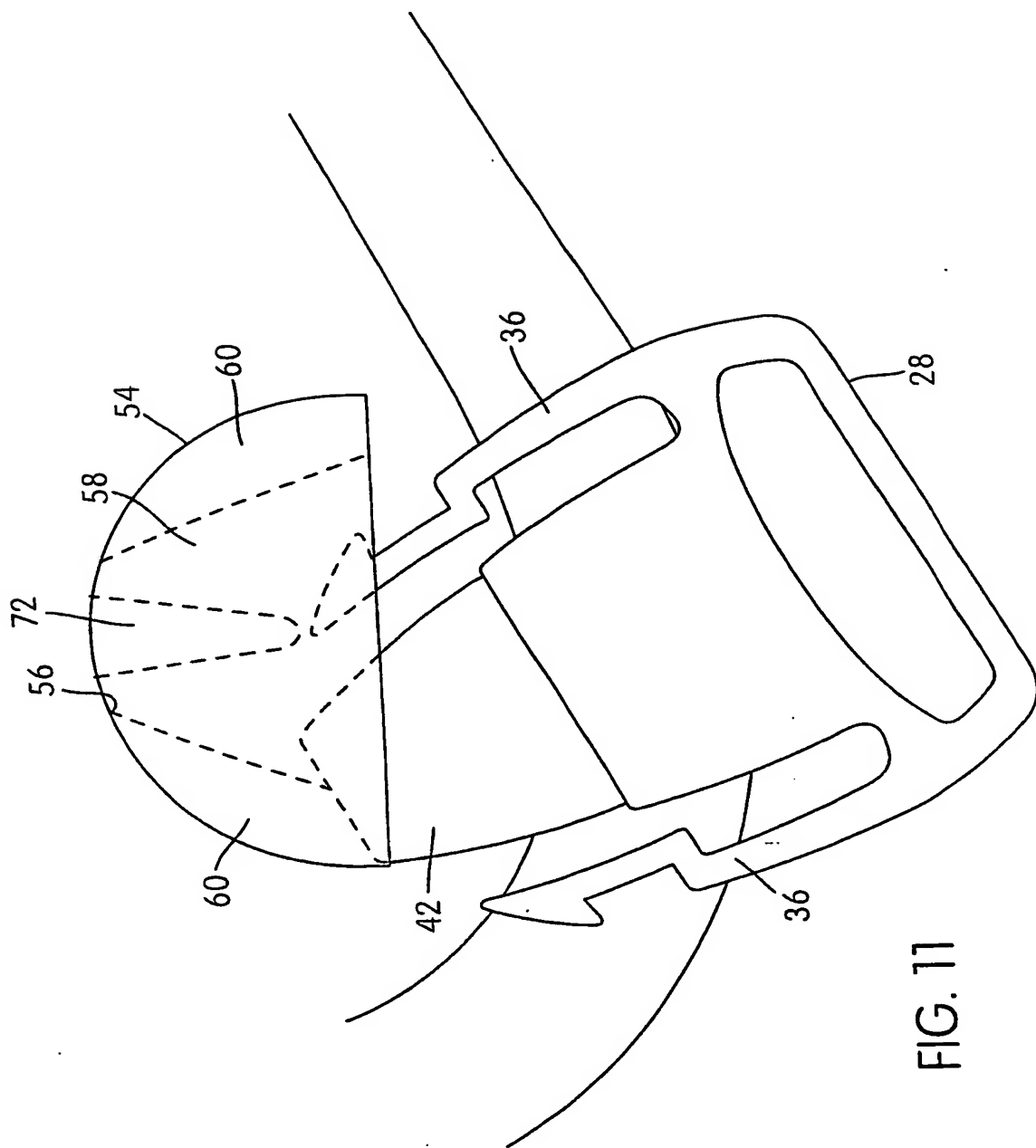
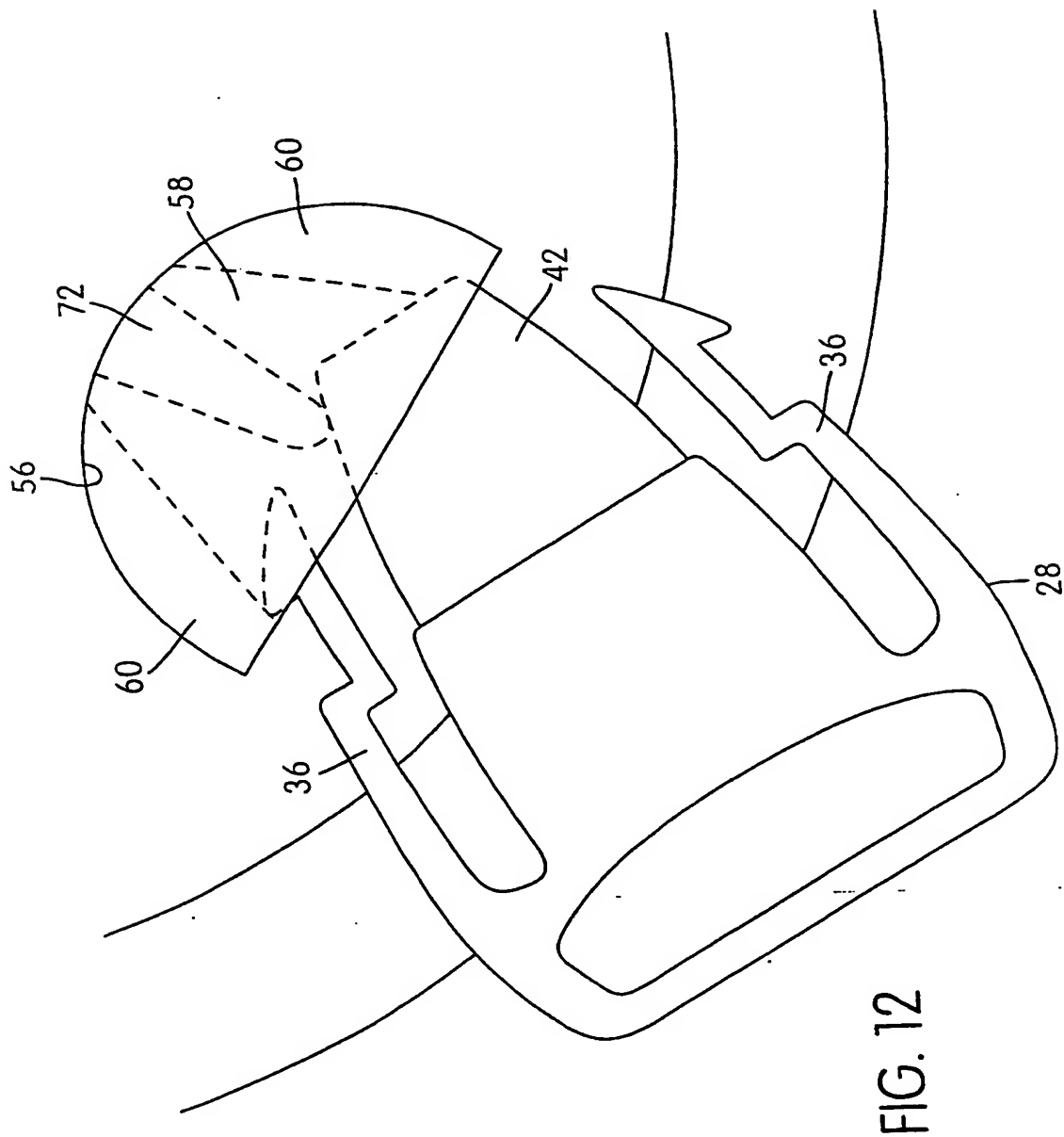


FIG. 10

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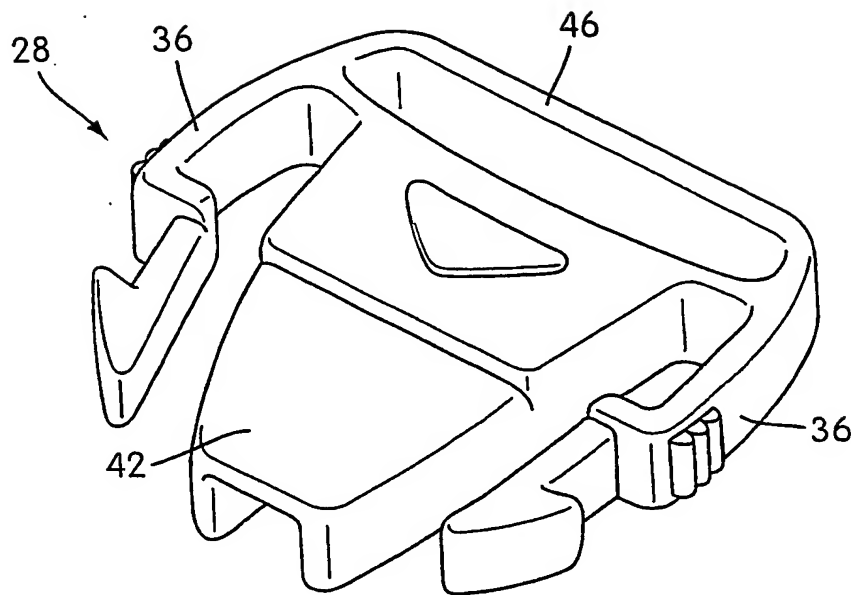


FIG. 13

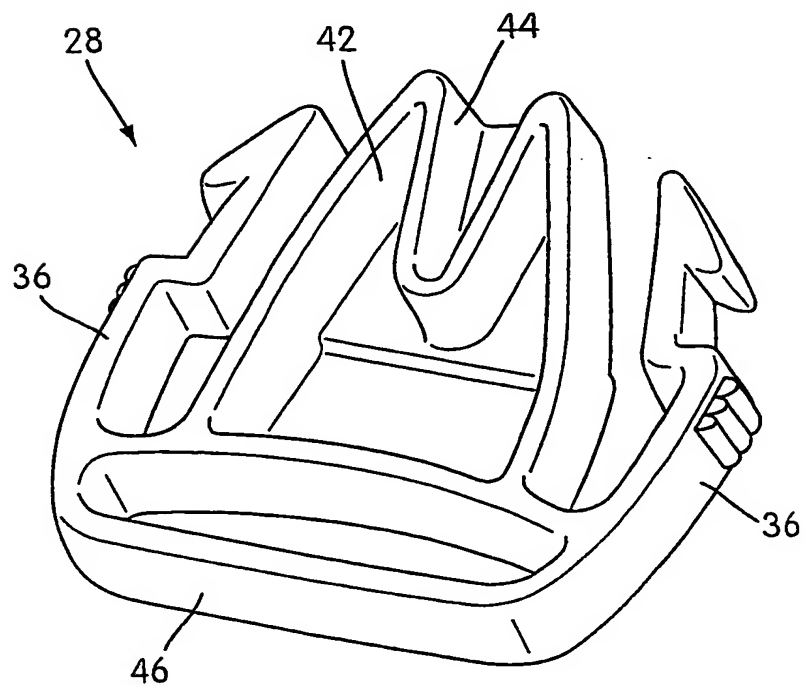
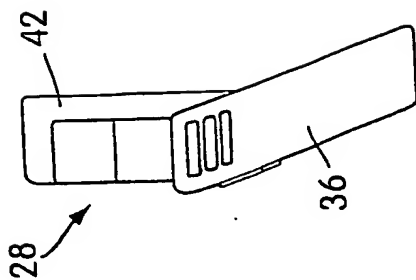
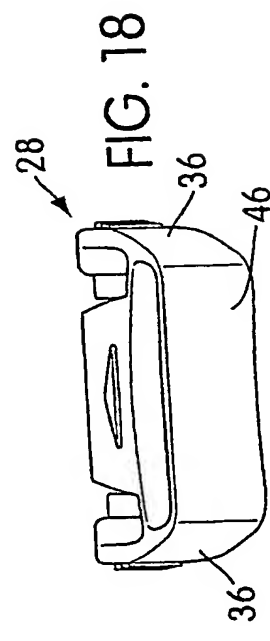
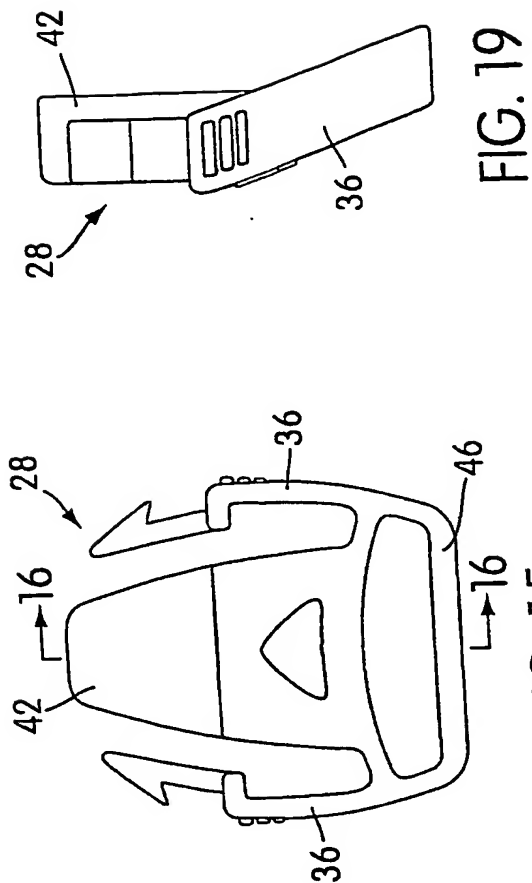
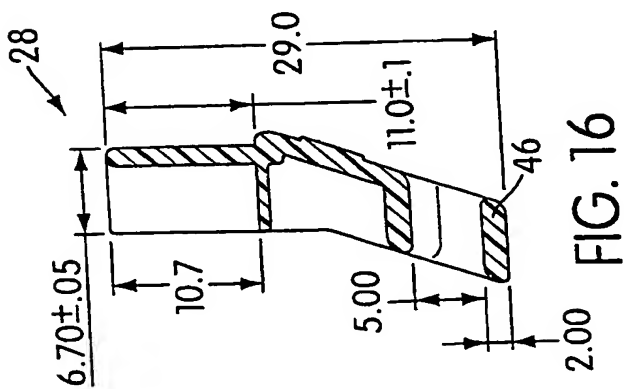
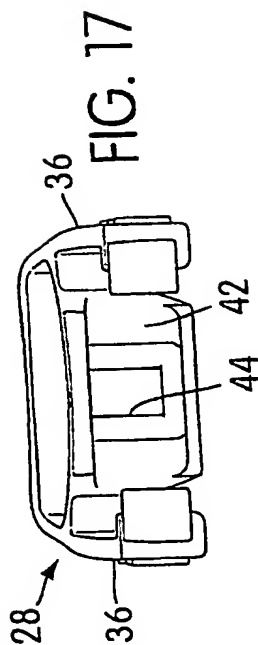


FIG. 14

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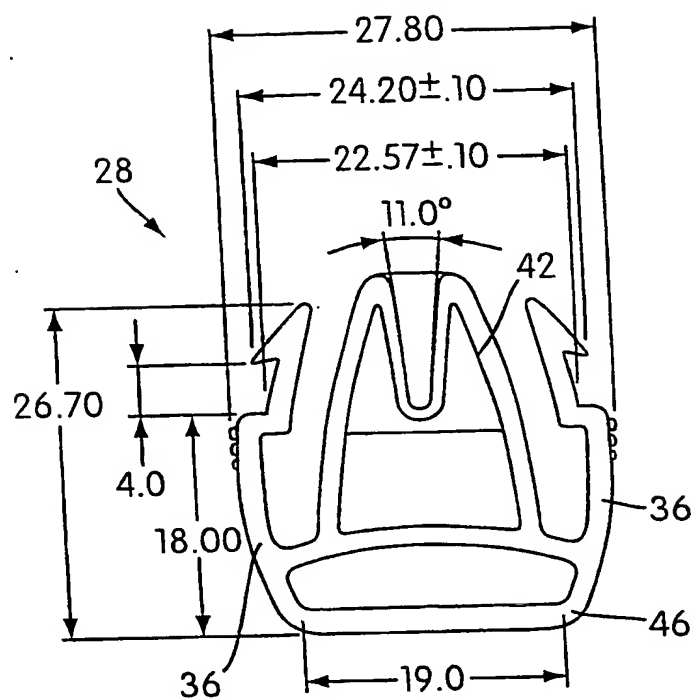


FIG. 20

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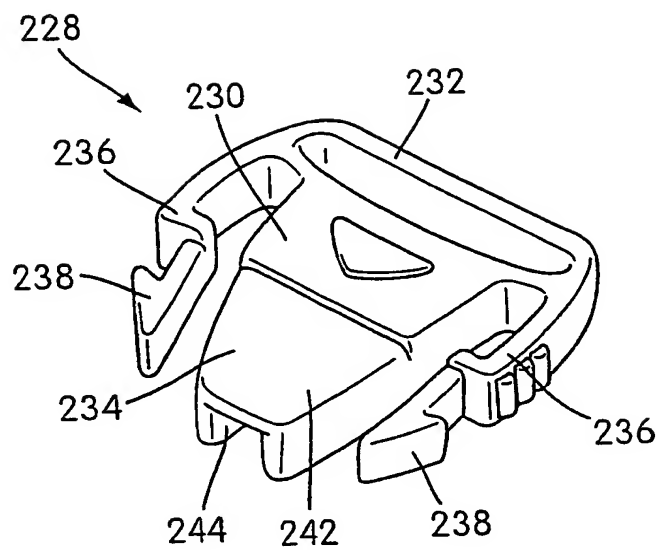


FIG. 21

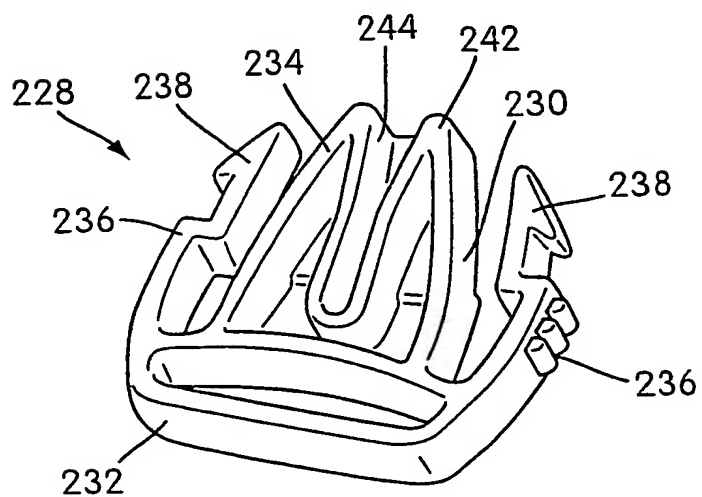


FIG. 22

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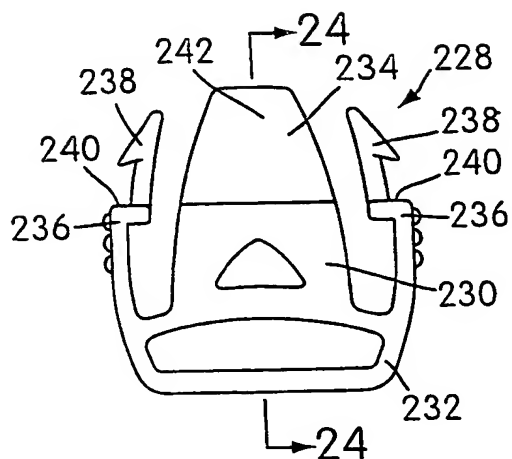


FIG. 23

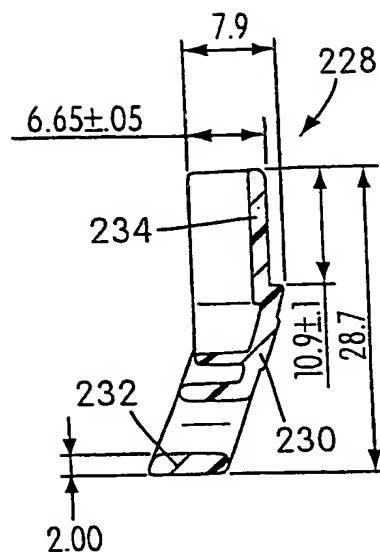


FIG. 24

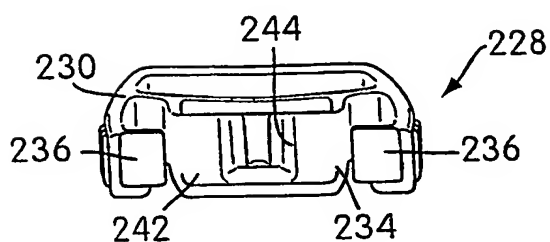


FIG. 25

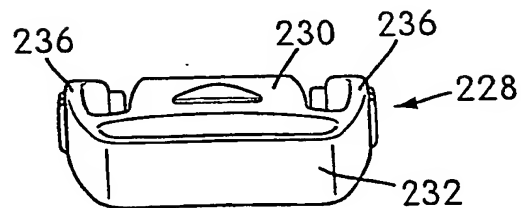


FIG. 26

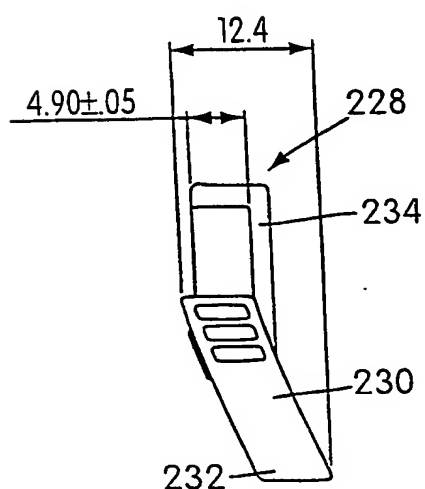


FIG. 27

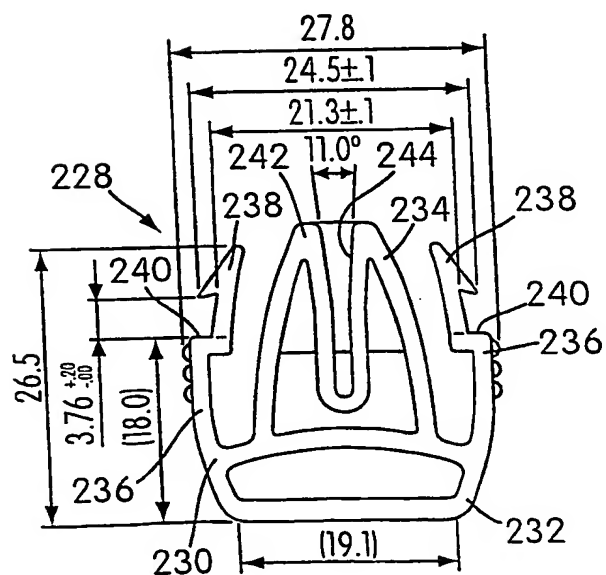


FIG. 28

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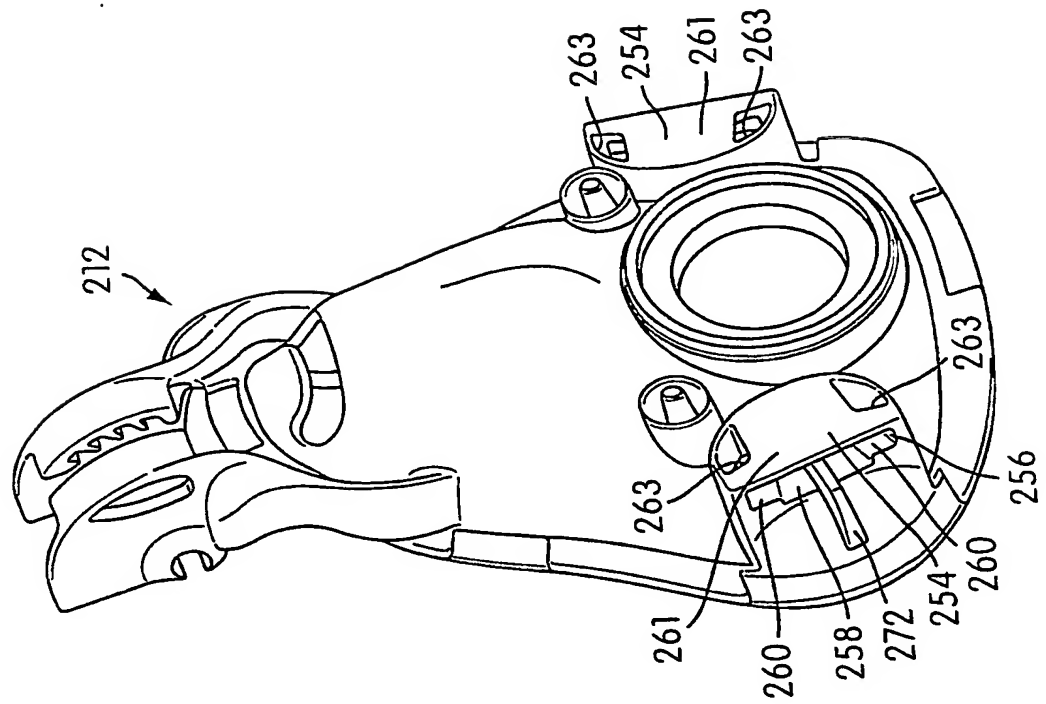


FIG. 30

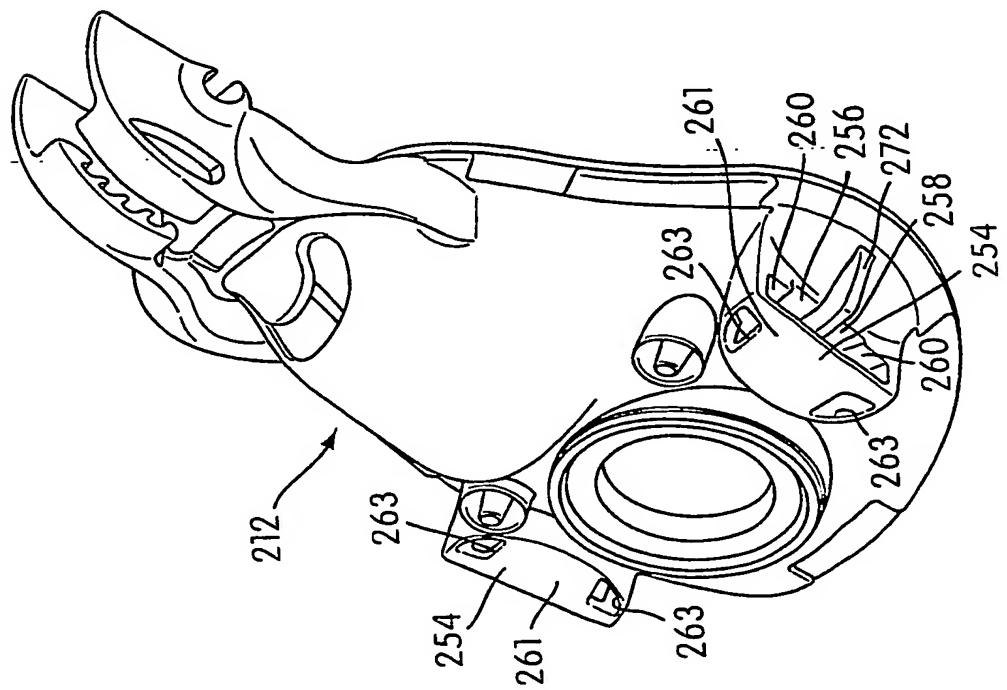


FIG. 29

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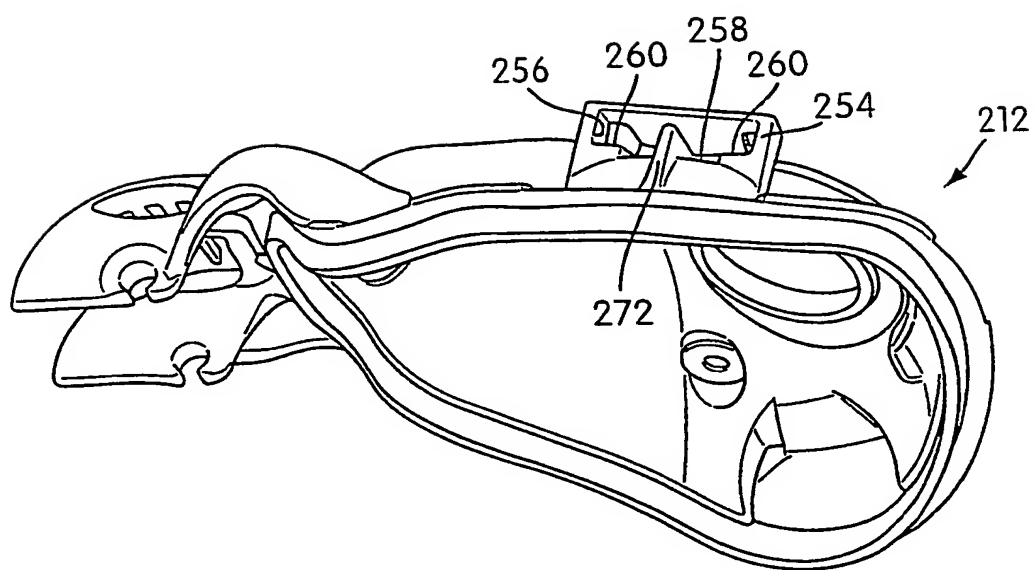


FIG. 31

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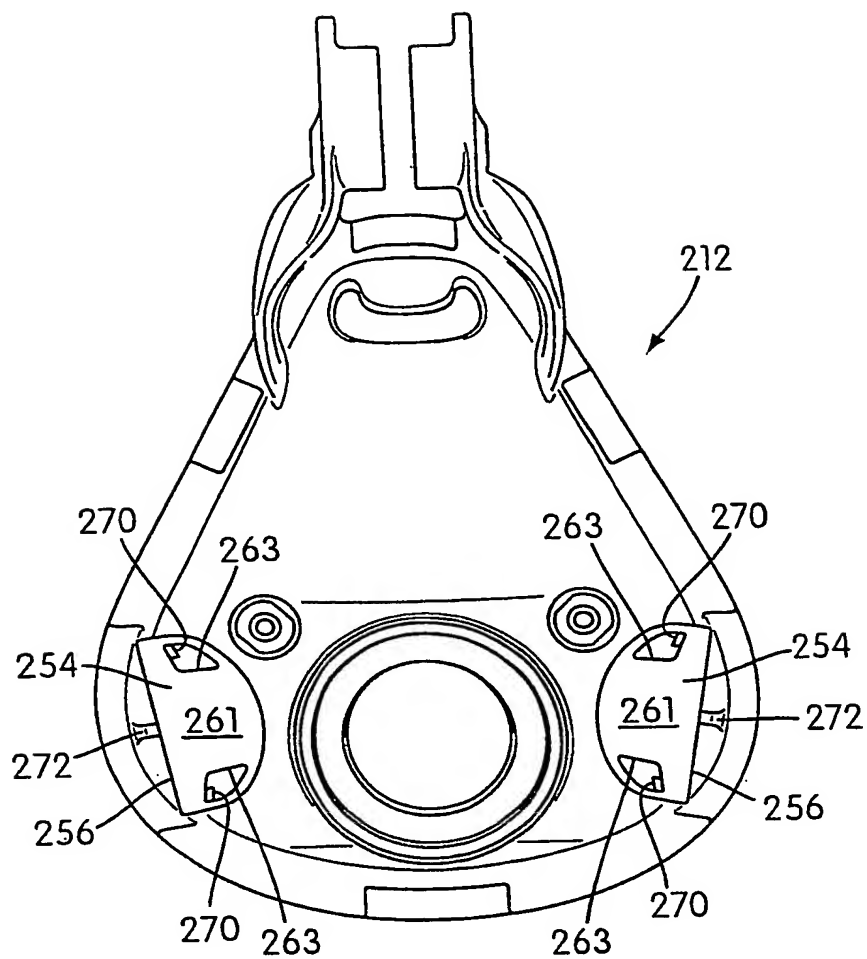


FIG. 32

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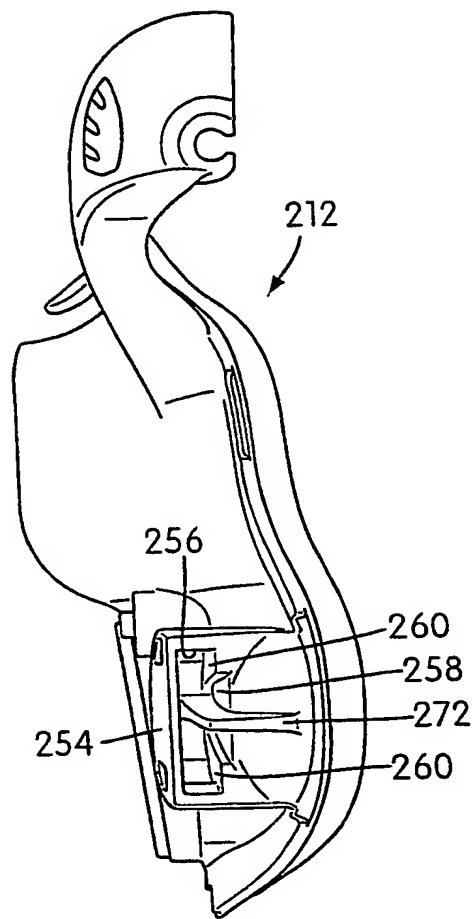


FIG. 33

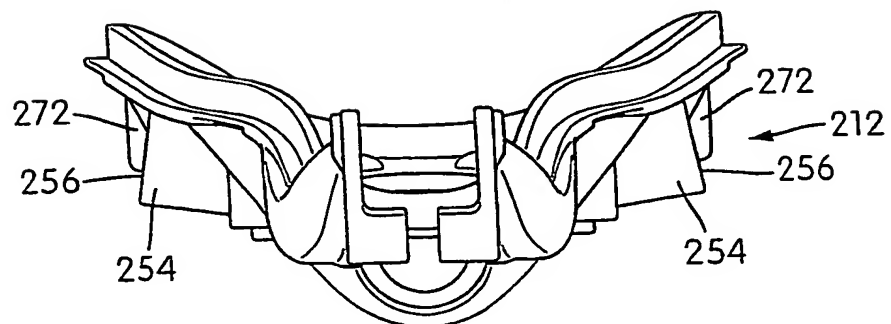
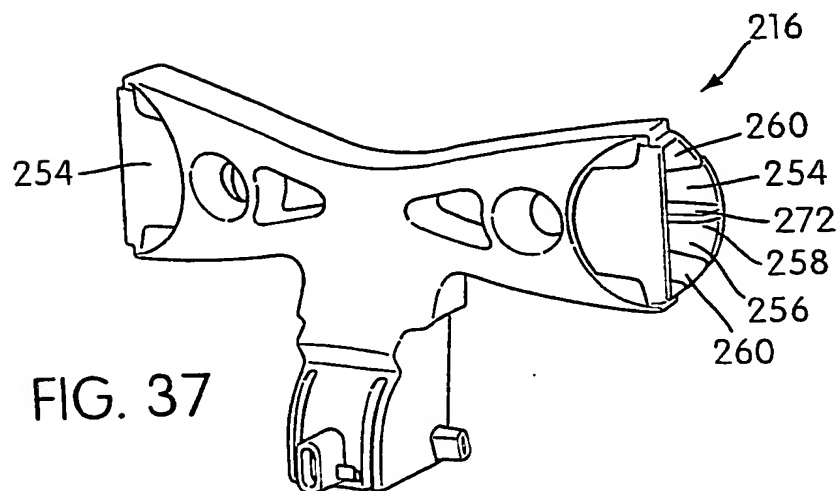
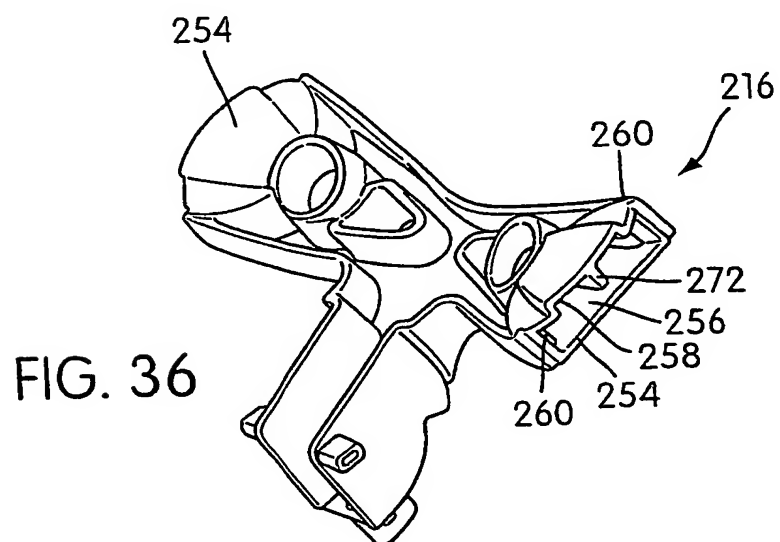
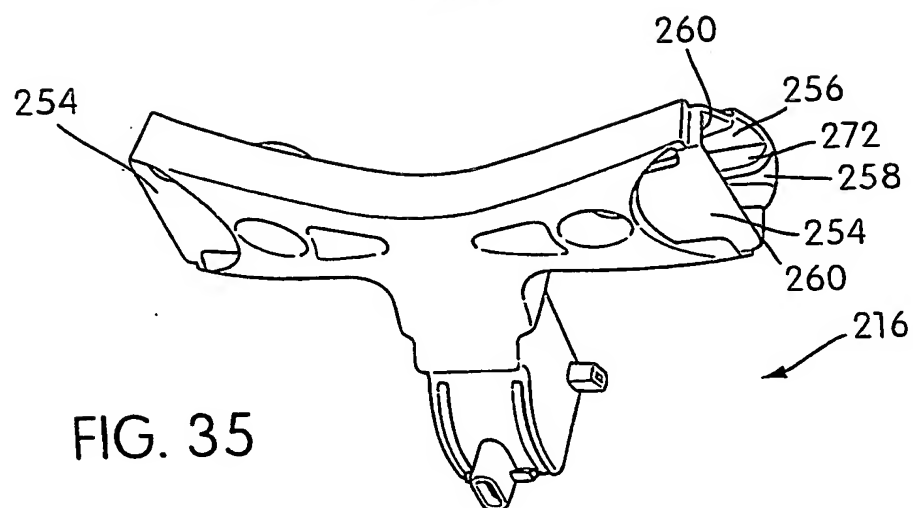
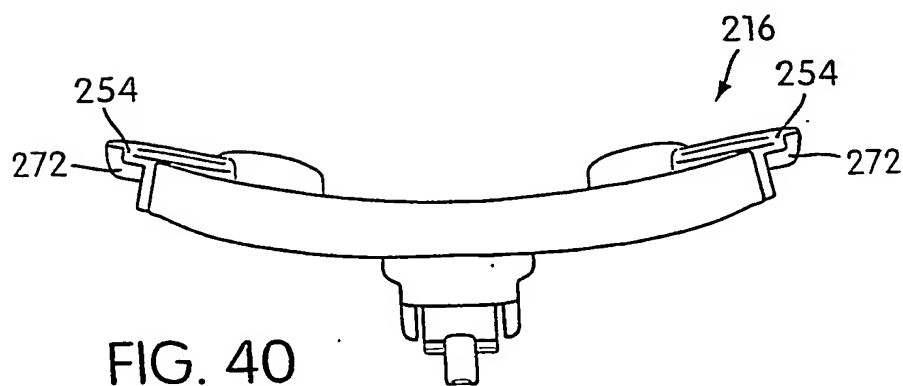
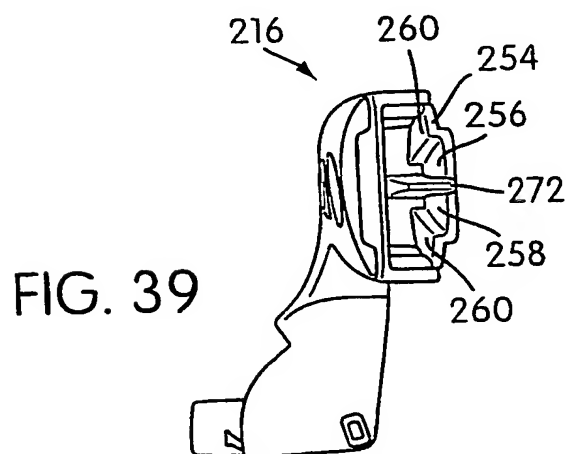
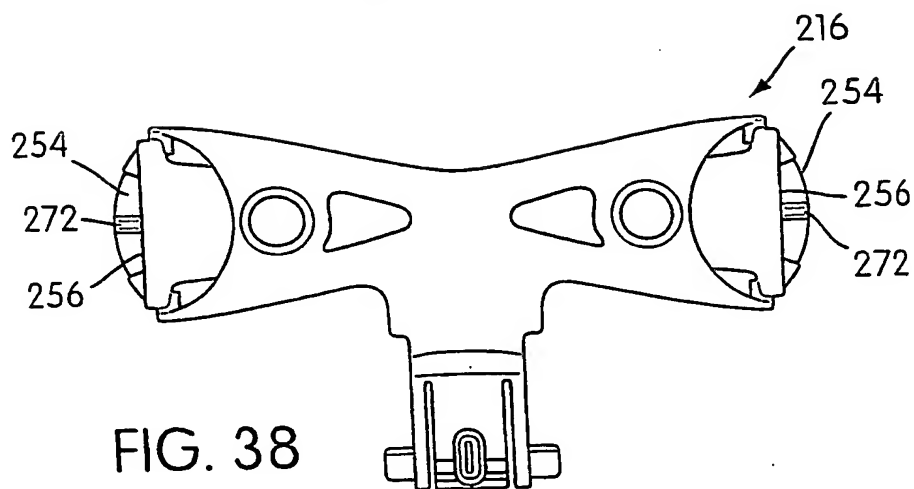


FIG. 34

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/01159

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61M 16/06 A44B 11/00 A62B 18/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols).

SEE ELECTRONIC DATABASES CONSULTED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

AU IPC: A61M 16/06 A62B 18/08 A44B 11/00, 11/10, 11/28 A45F 3/14 A41F 9/00

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI: A61M A61B A44B clip buckle clip clasp latch hook tongue snap mask strap headgear harness band belt frame head cranium skull

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/78384 A1 (RESMED LIMITED) 28 December 2000 Page 5 lines 10 to 16, figure 1	1-3, 12-17, 23, 31
X	US 6374826 B1 (GUNARATNAM et al) 23 April 2002 Figures	1-3, 12-14, 31
X	AU 41786/93 A (ILLINOIS TOOL WORKS INC.) 17 February 1994 Figures	15-23

☒ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
3 October 2003

Date of mailing of the international search report

16 OCT 2003

Name and mailing address of the ISA/AU

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Authorized officer


MATTHEW FORWARD

Telephone No : (02) 6283 2606

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/01159

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 30813/97 A (JOHNSON) 5 February 1998 Figures	15-23
X	WO 99/35933 A1 (McCAY HOLDINGS PTY. LTD.) 22 July 1999 Figures 1 to 4 and 11	15-23
X	FR 2676652 A1 (GALLET S.A.) 27 November 1992 Figure 1	24, 25, 31
A	DE 10057893 C1 (MPV-TRUMA GESELLSCHAFT FUR MEDIZINTECHNISCHE PRODUKTE mbH) 11 July 2002 Figure 1	1, 24
A	US 2002/0108613 A1 (GUNARATNAM et al) 15 August 2002 Figures 5a and 5b	1, 24

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/01159

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos : 27-30
because they relate to subject matter not required to be searched by this Authority, namely:
These claims combine features of a device with manufacturing steps. It is consider that such claims are unclear and do not satisfy Article 6 of the PCT
2. ☐ Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/01159

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 14 are directed to a mask assembly wherein the frame for the mask includes a locking clip receiving portion. A separate clip includes a cross bar and an opening through which the a strap of the headgear assembly may pass. It is considered that the receiving portion on the mask frame and the separate clip comprises a first "special technical feature".
2. Claims 15 to 23 recite a locking clip with a front portion including spring arms flexible within the plane of the main body of the clip and a rear portion having a cross bar and opening as defined in claim 1. It is considered that the features of the clip comprises a second "special technical feature".
3. Claims 24 to 26 define a mask assembly with a locking clip receiving portion attached to the frame and a locking clip with the front and rear portions disposed at an angle to each other. The angled locking clip constitutes the third special technical feature.
4. Claims 27 to 31 are directed to a mask frame and locking clip receiving portion molded as part of one unit. The frame includes an orifice surrounded by a collar. The special technical feature resides in withdrawing the opposed mold components apart along a single plane to separate the collar and locking clip receiver portion. This method step constitutes the fourth special technical feature.

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is a respiratory mask frame including a locking clip assembly. However this concept is not novel in the light of US 6374826 or WO 00/78384. Therefore these claims lack unity a posteriori.

Information on patent family members

PCT/AU03/01159

Patent Document Cited in Search Report		Patent Family Member			
WO 00/78384	AU 12454/97	AU 14892/00	AU 16355/00		
	AU 16811/02	AU 26505/00	AU 34293/97		
	AU 42476/99	AU 49012/00	AU 52005/00		
	AU 52007/00	EP 956069	EP 1027905		
	EP 1187647	EP 1187648	EP 1187649		
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	US 2002174868	US 2003034034	WO 00/78381		
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US 6374826	AU 12454/97	AU 14892/00	AU 16355/00		
	AU 16811/02	AU 26505/00	AU 34293/97		
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	US 2002153012	US 2002157672	US 2002174867		
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						END OF ANNEX

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